PHYSICIAN SELF-REFERRAL

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

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SUBMISSIONS FOR THE RECORD

PHYSICIAN SELF-REFERRAL

WEDNESDAY, MAY 3, 1995

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

The Subcommittee met, pursuant to call, at 9:30 a.m., in room 1100, Longworth House Office Building, Hon. Bill 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
April 18, 1995
No. HL-9

CONTACT: (202) 225-3943

THOMAS ANNOUNCES HEARING ON PHYSICIAN SELF-REFERRAL

Congressman Bill Thomas (R-CA), Chairman of the Subcommittee on Health of the Committee on Ways and Means, today announced that the subcommittee will hold a hearing on Physician Self-Referral. **The hearing will take place on Wednesday, May 3, 1995, in the main committee hearing room, 1100 Longworth House Office Building, beginning at 9:30 a.m.**

Oral testimony at this hearing will be heard from invited and public witnesses. 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:

The Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) barred physicians from referring a Medicare patient for clinical laboratory services to a medical facility in which a physician has a financial interest. The law included exceptions to the ban in order to accommodate certain business arrangements. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) expanded the restrictions to a range of additional health services and made the law applicable to Medicaid as well as Medicare.

Although the law is in effect, final regulations have yet to be issued on OBRA 1989 provisions and neither a proposed rule nor final rule has been issued on the restriction to other designated services included in OBRA 1993.

In announcing the hearing, Chairman Thomas said, "Without regulations, compliance with the self-referral laws isn't just a challenge, it's almost impossible. Furthermore, the law needs review because its prohibitions may be at odds with important efforts to encourage physicians to participate in more cost effective managed care arrangements."

FOCUS OF THE HEARING:

This hearing will examine problems associated with compliance with the self-referral provisions in the Social Security Act, the obstacles the law in its current form may present to physicians, hospitals, and health plans which are forming legitimate managed care arrangements, and will explore alternative methods of controlling the fraudulent and abusive referrals the law was intended to prevent.

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 at least six (6) copies of their statement, with their address and date of hearing noted, by the close of business, Wednesday, May 17, 1995, to Phillip D. Moseley, 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 typed in single space on legal-size paper and may not exceed a total of 10 pages including attachments.

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, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. 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 now available over the Internet at GOPHER.HOUSE.GOV, under 'HOUSE COMMITTEE INFORMATION'.

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Chairman THOMAS. The Subcommittee will come to order, please. Today the Health Subcommittee continues its review of Medicare policy with its hearing on physician self-referral. The original physician self-referral legislation was designed to respond to concerns over abuses, some real, some theoretical, arising from joint ventures between commercial clinical laboratories and joint venture partners, who were referring physicians. The intent of the legislation was to prohibit certain joint ventures, while attempting to allow limited exceptions for legitimate commercial arrangements.

Before the HCFA, Health Care Financing Administration, implemented this first physician self-referral limitation, the law was greatly expanded by the OBRA, Omnibus Budget Reconciliation Act of 1993. OBRA 1993 includes prohibitions on financial arrangements which encompass the majority of therapeutic and diagnostic services provided to Medicare and Medicaid patients.

The new law goes beyond the original concern with abusive joint ventures by adding detailed regulation of the internal workings of physician group practices, hospital, medical schools, and entities that employ or contract with practicing physicians. The two major changes have raised concerns that the law now may be overreaching, perhaps too complex, and too intrusive. Proof of the complexity is illustrated in HCFA's apparent difficulty to develop a final rule for the 1989 law and promulgate even proposed implementing regulations for the OBRA 1993 amendments today almost 2 years after enactment.

Further, concerns have been raised that the OBRA amendments have had a chilling effect on legitimate and worthwhile physician participation in the emerging competitive health care marketplace. In some ways the law perhaps may already be antiquated. Managed care is a reality for the private sector and is growing rapidly for public programs and simply does not have the same incentive structure which physician self-referral law was designed to limit.

Today, we will hear about the difficulties of developing the physician self-referral regulations and from witnesses who have tried to understand the law and apply it to routine physician employment and contracting situations. We should learn today whether the physician self-referral law is relevant and what should be modified, if anything, to make it more compatible with appropriate innovations in the delivery of medical care to Medicare beneficiaries and to all Americans. I would call on my colleague, the Ranking Member, Stark I and Stark II.

Mr. STARK. Thank you, Mr. Chairman. If I promise to not use hardly any time at all in inquiring during the course of the day, maybe the Chair will indulge me for a little bit longer than usual in my opening statement from which I have tried to cross all of the phlegmatic and vitriolic phrases.

Chairman THOMAS. Would the gentleman yield?

Mr. STARK. I would be glad to yield.

Chairman THOMAS. With unanimous consent, if we could shorten the questioning period to 4 minutes for each Member, the time is yours.

Mr. STARK. I am sure that we have no objection. I have a prepared statement which I would like to be made a part of the record,

and I would like to concur with the Chair, disavow what is left of my good name from the legislation and see if I can bring the present situation into perspective.

It is true that I chaired this Subcommittee when this law was written, and I suspect tradition may have accorded me the dubious distinction of having the bill named after me. The idea for the bill was brought to us by the Inspector General in a Republican administration, and the bill was agreed to originally by the then Ranking Member and the Chair, and I believe fairly unanimously in the Subcommittee because there were abuses to the billing system in Medicare. There were detailed and voluminous studies made subsequent to the legislation, and initially or prior to the legislation, which indicated something like 50 percent higher usage and higher costs for clinical labs by doctors who owned a piece of the lab. We held off covering any other procedures until we had evidence.

I have got a room full of anecdotes somewhere around here from people who sent them in, but when we had studies, we went to some length to require certain detailed financial information from physicians and so forth. The AMA will tell you later today, as their usual revision of history, that they supported the law and said this practice was unethical. They came rather late to that.

First, they said that we ought not to restrict referral. Then they voted again and decided maybe it was unethical. We were here to protect, one, the Medicare patients and, two, the system and the trust fund.

I have always taken this position. Once we set a law down to restrict referral, we created a handbook for lawyers to find a way around the law. It wasn't really the law's fault. I have always believed that if we choose not to limit investment in facilities to which a physician refers, then we ought to just open it up and have sunshine.

If my son, as has happened, fell off a horse, had a concussion, and I had to deal with radiologists and neurosurgeons through the interpretation of his pediatrician, and the pediatrician spent hours telling me, a very distraught father, what was wrong with my son. I could make the case that perhaps that pediatrician should have had a cut of the radiologists' fee. If this is the case, institutionalize it and say, OK, we will pay a collaborative fee. The problem is that when we are spending the public's money on Medicare, we have to know what we are getting for that money, and to some extent we have a responsibility to protect the patient.

This is just some of the background. We received more evidence from the studies that there were further abuses—when I say abuses, I mean that there was empirical evidence in a broad scale documenting that where there was ownership there were higher costs and higher utilization than otherwise was the norm in the country. These were not anecdotal. This evidence came from studies.

We think there were savings approaching $1.5 billion by writing this law. We do not think that we were chasing a hollow specter. We think there were instances where this was necessary. I would like to see the law simplified if that is possible. I would lay the blame for the lack of simplification on hysterical lawyers drumming up business, quite frankly.

There are more seminars around that you can go to on Stark I and Stark II and pay thousands of dollars to lawyers who can over complicate. HCFA is remiss for not getting the regulations out. I want to commend the Chair for these hearings in the nature of oversight, but I urge you to not get swayed too much by the anecdotes which you will hear on both sides. The question, as the Chair has indicated, as we move to managed care, is whether there is a tendency to want to buy doctors' practices to get at the patient lists.

Is that a referral in reverse? Do we care? Does it impact on the patients? I do not know. I think those are questions to which we may want to know the answers. I just wanted to say that I do not think there are two positions or three positions in this issue. I think there are some people who have justifiable grievances because we, the government, the administration and the Congress have not simplified, sorted through, adjusted and revised the law in a timely manner.

I think the patients are ripped off every now and again, and I think some of the specialty groups lose their ability to make money because the doctors who control—the physical therapists, for instance, generally only get to practice their profession if doctors refer—only refer to themselves. If the doctor owns the practice, the physical therapists who are independent have a legitimate gripe.

I hope you will listen to all of the testimony today and not try and classify this as government regulation against entrepreneurs. It is more complex than that, and not each group is neither a charlatan nor a knight in shining armor. It is an area that is of concern, and I hope that we can urge HCFA to complete regulations much more rapidly. We can look at the regulations and then legislate to make the changes that you all feel are necessary. Thank you, Mr. Chairman. I yield back whatever time I have abused.

[The opening Statement follows:]

OPENING STATEMENT OF CONGRESSMAN PETE STARK
PHYSICIAN SELF-REFERRAL

Mr. Chairman:

Over the past 6 years, this Committee has approved and amended this legislation because we felt strongly that a physician's ability to buy and sell patients is bad for the public and bad for the patient.

Physician self-referral is bad for the public because it inevitably encourages unnecessary duplication and overutilization of facilities and services, producing an overall significant increase in cost to the patient. In 1993, when the physician self-referral law was expanded, CBO projected that the Medicare program would save $350 million dollars over five years.

These arrangements are bad for the patient because they violate the understood principle between patient and physician -- physicians should be paid only for the services to their patients which they provide directly or which they supervise. The physician should honor the fiduciary relationship that exists between physician and patient. These unethical arrangements give doctors powerful incentives to bend their professional judgment. Without laws to prohibit abusive arrangements, doctors will continue to drift toward the opinion that medicine is just a business, and patients are theirs to be bought and sold.

The physician self-referral law is nothing but a logical extension of what has traditionally been viewed as part of the physician's professional code of ethics. The AMA's Judicial Council itself has recognized that conflicts may arise when physicians derive economic benefits from commercial ventures involving their patients. The Institute of Medicine recognized the conflict of interest in 1986 when it stated: "It should be regarded as unethical and unacceptable for physicians to have ownership interests in health care facilities to which they refer patients."

In 1989, the OIG issued a study that found that patients of referring physicians who own or invest in independent clinical labs received 45% more clinical laboratory services than all Medicare patients in general. This study was only the beginning - study after study has documented the numerous abuses in this area. Researchers in Florida found that forty to forty-six percent of physicians in Florida owned an interest in a joint venture, and that referring physicians owned, in whole or in part over ninety percent of all diagnostic imaging centers, over seventy-five percent of all ambulatory surgical facilities, and about half of the radiation therapy centers and clinical laboratories in the state. These doctor-owners consistently ordered more tests and more expensive tests than non-owners.

Researchers in California found that physician owners of physical therapy centers referred patients for physical therapy more than twice as often as other physicians. A study of radiation therapy showed that patients with similar symptoms were at least four times more likely to have diagnostic imaging performed if a physician self-referred.

The studies go on and on ...

I believe that, as with any major piece of legislation, clarifications may be required after enactment. But let me be clear -- the documented abuses in this area have convinced me that at this time, patients need protection more than doctors need the income. I hope that the revisitation of this issue is motivated solely by an interest to perfect the law and not to repeal it.

The delay in releasing the regulations has contributed to both the confusion of the doctors and to the bank accounts of the lawyers. It is unacceptable that it has taken HCFA over five years to release the regulations for the initial self-referral law. The regulations for the other designated health services must be released in a more timely manner -- this summer at the latest.

There are areas of confusion. For example, several physicians have called asking why they are prohibited from giving a patient with a broken leg a set of crutches in his office. This is an example of an unintended consequence. Let's work together to fix this problem quickly. I've also heard that the law has been interpreted to prohibit physicians from providing eyeglasses or IOLs after cataract surgery. Well, if this is what is happening, we need to clarify the law.

Some of the concerns that I hear are valid -- most of the concerns result from very imaginative lawyers. Unfortunately, the ability of lawyers to be "creative" has resulted in wide-spread hysteria about the impact of this law.

I agree that some clarifications are needed, but let me cite just an example or two of the suggested changes that have been sent to my office. One organization suggests that we repeal all reporting requirements. Well, let's imagine this scenario for just a moment. If we said to physicians, "O.K. -- We'll trust you - don't report your financial interests." I don't have much faith that doctors would comply with the law without reporting requirements. How would HCFA or OIG know if anyone was ever in violation?

Another interesting suggestion provided by an organization requests that we eliminate seven of the designated health services. Well, if we do that, most of the law has been eliminated. We might as well repeal the entire thing and return to unbridled over-utilization and over-treatment of patients.

What I suggest is that we look at the overwhelming evidence of abuse in this area. We must clarify where necessary without creating loopholes that would essentially negate the law.

Last year, we worked extensively with a number of provider groups and organizations to draft amendments during health reform that unfortunately did not pass. The American Group Practice Association was very helpful in drafting a clearer definition of "group practice" for example, and I would hope that we would consider a number of the clarifications addressed last year.

Physicians can act as stronger advocates for their patients if they do not refer patients to entities in which they have a financial interest -- it is, simply put, a conflict of interest. Independent physicians are more likely to provide neutral advice, and more apt to be sensitive to the needs of patients if they have to earn their referrals through their reputation for quality.

Physician self-referral has no inherent social value, biases the judgment of physicians, and compromises their loyalty. Physicians are only human. If a doctor has an outside financial interest, there is always the risk that his or her professional judgment will be unduly influenced. Dr. Arnold Relman said it best in 1989 – "We cannot make individual physicians more ethical by making laws or regulations, but we certainly can legislate against economic arrangements that tempt them into undesirable behavior."

Chairman THOMAS. I Thank the Ranking Member very much. I am very pleased with the tone of the opening remarks because it clearly was not our intention in moving forward in this area to create more problems. It is an attempt to understand and solve problems.

I think everyone agrees in an a priori way that where someone has an ability for self-aggrandizement simply by patronizing their own actions, their is the potential for problems. Our concern is with the manner in which it was constructed, the methodology of the materials supporting the positions that were taken, and the difficulty in getting some of the regulations formulated. The witness that will be with us shortly, I think, will commiserate with us in terms of the difficulties of putting the package together. And that the goal of this hearing is, to improve product, not to eliminate product.

And with that, I would ask our first witness, Kathy Buto, who is the highest career person in HCFA, if you have a written statement, we will place it in the record without objection, and you may proceed in any way you see fit to inform us, Ms. Buto.

STATEMENT OF KATHLEEN A. BUTO, ASSOCIATE ADMINISTRATOR FOR POLICY, HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. BUTO. Thank you very much, Mr. Chairman, and Members of the Subcommittee. I am here to discuss HCFA's implementation of the physician self-referral prohibitions found in section 1877 of the Social Security Act, and I am going to keep my remarks short and ask that my written testimony be entered into the record.

The Clinton administration has been working on a number of initiatives to control fraud and abuse in the Medicare and Medicaid Programs. In fact, we will soon be announcing a comprehensive proposal for program integrity as part of our effort to reinvent government. Preventing inappropriate utilization through a prohibition on self-referrals is just one component of our campaign.

This morning, I will discuss why we believe there is a need for self-referral limitations, and review the legislative history and our regulatory activity. Self-referral is the term used to describe a patient referral made by a physician to an entity with which the physician or family member has a financial relationship.

The relationship may be an ownership or investment interest or a compensation arrangement. The American Medical Association estimates the number of physicians with financial interests in health facilities at about 7 percent. Other studies cite numbers as high as 40 percent.

A 1989 study from the Office of Inspector General of the Department of Health and Human Services found that Medicare patients of referring physicians who owned or invested in independent clinical laboratories received 45 percent more lab services than Medicare patients in general. This increased utilization cost the Medicare Program an estimated $28 million in 1987.

Aside from the cost containment issues posed by self-referral patterns, inappropriate utilization may result in health hazards. Broadly stated, beneficiaries caught in these referral patterns may

be subject to unnecessary medical procedures and/or high cost, lower quality care. Ethicists and legal scholars have argued that self-referral creates an unnecessary conflict of interest.

Physicians are members of a profession that is characterized by binding ethical obligations and a unique responsibility to care for patients who are presented to them. Indeed, the AMA has stated that physicians, "have different and higher duties than even the most ethical businessperson."

Patients depend on their physicians to guide them in making health care decisions, yet when physicians stand to benefit financially from referrals made for certain health care services, it raises questions about whether the referral is being made because of medical necessity or financial interest.

As early as 1986, the Institute of Medicine strongly condemned physician self-referral in its examination of for-profit enterprise in health care, citing among other things the unique and vulnerable position that patients are in while making health care decisions.

In December 1992, after considerable debate the AMA took a firm stand against self-referral, recommending only one limited exception for community need when alternative financing is not available. Their Council on Ethical and Judicial Affairs stated that physicians have a special fiduciary responsibility to their patients and "there is some activities involving their patients that physicians should avoid, whether or not there is evidence of abuse."

Prohibitions on self-referrals were created in the context of a traditional fee-for-service Medicare system where there are no incentives for providers to control utilization. In a managed care arrangement that uses capitated payments the implications of self-referral practices change considerably. It is highly unlikely that physicians who are receiving a capitated payment would actually refer for unnecessary services.

Accordingly, there is an exception for prepaid health plans that contract with Medicare, including risk and cost-based Medicare contractors. Therefore, we do not see these provisions as an impediment to the development of legitimate Medicare managed care arrangements.

The initial prohibition on physician self-referrals was created in the Omnibus Budget Reconciliation Act of 1989, and applied to clinical laboratories in the Medicare Program. The law has subsequently been modified in every piece of major Medicare legislation that has passed since its creation—OBRA 1990, OBRA 1993, and the Social Security Act amendments of 1994.

OBRA 1993 made the most significant changes by adding a list of 10 additional designated health services expanding and clarifying the exceptions and applying certain aspects of the law to Medicaid referrals. Because of its exceptions, the current law is complicated. However, the essence of the prohibition is clear if a physician or a family member has a financial relationship with an entity that furnishes items or services on the list, then he or she cannot refer Medicare or Medicaid patients to that entity.

Unlike the antikickback statute, the law is triggered by the mere fact that a financial relationship exists. The intention of the referring physician is not taken into consideration. The provisions state

that the relationship may be through an ownership or investment interest or a compensation arrangement.

The ownership or investment interest may be through debt, equity or other means or an interest in an entity that holds such an interest. The compensation arrangement is defined as any remuneration between the physician or immediate family member and the entity that does not fit within the specified exceptions.

OBRA 1989 provisions and many of the OBRA 1993 provisions that apply to the exceptions for clinical labs became effective for referrals occurring on or after January 1, 1992. OBRA 1993 provisions that apply to referrals for designated health services became effective January 1, 1995.

Although some inappropriate utilization may exist, Congress created a number of exceptions in recognition of existing business practices, the in-office ancillary services exception is perhaps the most important exception. It exempts physicians, both group practices and solo practitioners with ownership and/or compensation arrangements from self-referral ban from most services provided in their offices if they meet a set of requirements.

The statute also prohibits an entity from billing or influencing billings to Medicare or Medicaid, the beneficiary or anyone else for a designated health service resulting from a prohibited referral. Under the Medicaid Program the Federal Government cannot pay Federal financial participation to a State for medical assistance that is furnished as a result of a referral that would be prohibited under Medicare if Medicare covered the service in the same way as a State Medicaid Program.

If a person collects any amount for services billed in violation of the law, he or she must make a timely refund. A person can be subject to a civil money penalty or exclusion from Medicare, Medicaid or other programs violating these provisions.

Let me turn to the regulations. We are faced with twin challenges as we try to implement this law. First, while the basic concept is simple, the legislative process created complicated exceptions. Adequately defining these exceptions has proven to be a daunting task that has played an important role in the development of the accompanying regulations.

Second, the repeated modifications of the underlying legislation that I mentioned earlier have further delayed and complicated issuance of the implementing regulations. We are issuing two separate rules. The first for provisions that are related to referrals for clinical lab services, and the second for provision of the designated health services.

The proposed rule for the original legislation was published in spring 1992. We have received more than 300 comments on the proposed rule, many of which included multiple technical questions, each of which needed to be addressed in detail. These comments included detailed descriptions of practical considerations that required recognition in the rule.

Most responses to these comments needed to be recast or entirely rewritten after the OBRA 1993 changes. In addition, we have spent a significant amount of time meeting with and talking with individual practitioners, providers, their attorneys, and industry associations in an attempt to deal fairly and proactively with issues that

are raised by the law and subject to interpretation in the regulations. Many of these discussions have focused on reviewing individual situations that do not fit clearly within one of the stated exceptions, but which have the same or similar situations as those provided for in the exceptions.

Thus, the final rule for self-referral provisions for clinical lab services is under review, and we hope to publish it shortly. The rule contains many definitions and interpretations that will apply to referrals for all designated health services. As a result, we expect it to answer many questions for situations prohibited under the law as currently written.

In addition, our conversations with the provider community have also dealt with interpretation of the changes made in OBRA 1993. These outreach efforts have helped us prepare for the development of the second set of regulations. Once the final rule is published, we hope to publish a proposed rule for the remaining provisions that are related to the designated health services within a few months. At this point, we estimate we will publish the proposed rule by the end of the summer.

As I am sure you know, the provider community is concerned about enforcement. We do not have discretion to alter the effective dates, and while we recognize that the complexity of the law raises many questions about how it is to be applied, it is nonetheless in effect. We intend to implement the law using the least burdensome manner that will still allow for effective enforcement.

As we stated in a summary that we sent to provider groups, Medicare carriers, and fiscal intermediaries and other interested groups in January, we will begin compliance audits once the final rule for clinical labs is published. In addition, we will investigate reported abuses.

In summary, we feel that appropriate referral guidelines are necessary to preserve the integrity of the programs that we oversee. As I mentioned earlier, we are in the process of implementing a cost-effective effort to combat fraud and abuse in the Medicare and Medicaid Programs. Limiting abusive self-referrals is and should remain an integral part of that effort. I am happy to take questions, Mr. Chairman.

[The prepared statement follows:]

TESTIMONY OF KATHLEEN A. BUTO, ASSOCIATE ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairman and members of this subcommittee, I am here this morning to discuss HCFA's implementation of the physician self-referral prohibitions that are found in section 1877 of the Social Security Act.

The Clinton Administration has been working on a number of initiatives to control fraud and abuse in the Medicare and Medicaid programs. In fact, we will soon be announcing our comprehensive proposal for program integrity as part of our Reinventing Government efforts.

Preventing inappropriate utilization through a prohibition on self-referrals is one part of our coordinated effort to fight fraud and abuse. Today I will be focusing on the self-referral provisions, as you requested, and not the anti-kickback provisions, which are frequently confused with self-referral.

I would like to recognize the interest and responsibility of this Subcommittee in the development and passage of these provisions. I will begin by presenting a bit of background information, discussing the research and related ethical issues which form the basis for why we believe self-referral limitations are needed; following this, I'll briefly summarize the law and our regulatory activity.

BACKGROUND AND RESEARCH

Self-referral is the term used to describe a patient referral made by a physician to an entity with which the physician or a family member has a financial relationship; the relationship may be an ownership or investment interest or a compensation arrangement.

Physicians who invest in health care entities are likely to have ownership or investment interests in magnetic resonance imaging (MRI) centers, other diagnostic imaging facilities, clinical laboratories, ambulatory surgical centers, or physical therapy facilities. Hospital-physician joint ventures are also a common form of financial relationship; the General Accounting Office (GAO) estimates that 18 percent of non-profit hospitals were participating in joint ventures with physicians in 1991.

The American Medical Association (AMA) estimates the number of physicians with financial interests in health facilities at about seven percent, although others cite higher numbers. For example, a 1991 study that examined the prevalence and scope of physician joint ventures in Florida found that at least 40 percent of Florida physicians involved in direct patient care had an investment in a health care business to which they could--in the absence of prohibiting legislation--refer patients for services.[1] However, some have suggested that increased examination of self-referral arrangements and enactment of both Federal and State laws prohibiting such arrangements has led to a decline in self-referral activity and financial relationships between physicians and entities.

In 1989, a study from the Office of Inspector General (OIG) of the Department of Health and Human Services found that Medicare patients of referring physicians

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[1] "Joint Ventures Among Health Care Providers in Florida," State of Florida Cost Containment Board (September, 1991)

who owned or invested in independent clinical laboratories received 45 percent **more** lab services than Medicare patients in general.[2] OIG estimated that this increased utilization cost Medicare $28 million in 1987. While this report does not examine medical necessity, it clearly shows a significant deviation from general medical practice. More importantly, it illustrates the need for provisions that limit the acceptability of unnecessarily costly referral patterns.

In past hearings on this topic, this Subcommittee has heard testimony from academic researchers in Florida and from the GAO and the OIG, among others, that consistently cited problems in referral patterns for physicians who have financial relationships with the entities to which they refer patients. The problems include increased utilization, increased use of costly services, and, in some cases, higher charges per procedure, decreased access, and lower quality (e.g., less time spent with the patient or patient care is provided by health care personnel with less training). Broadly stated, beneficiaries caught in these referral patterns may be subject to unnecessary medical procedures and/or high-cost, lower quality care.

Aside from the cost-containment issues posed by self-referral patterns, inappropriate utilization may result in health hazards. Each time certain medical procedures are performed, patients could be exposed to an increased risk of injury. One study of physician ownership actually showed that the frequency and costs of radiation therapy treatments at free-standing centers were 40 to 60 percent higher in Florida than in the rest of the United States, yet Florida did not have higher cancer rates and the hospitals in the study did not have below-average use of radiation therapy to explain the higher use or higher cost.[3]

ETHICAL ISSUES

Ethicists and legal scholars have argued that self-referral creates an unnecessary conflict of interest without providing any significant benefits. Physicians are members of a profession that is characterized by binding ethical obligations and a unique responsibility to care for patients who are presented to them. Indeed, AMA has stated that physicians "have different and higher duties than even the most ethical businessperson."[4] Physicians direct the purchase of health care services. Patients depend on their providers to guide them in making health care decisions. Yet, physicians investing in health care services that they refer to, at a minimum, raise perception concerns as to whether the referral is being made because of medical necessity or financial interest.

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[2]"Financial Arrangements Between Physicians and Health Care Businesses," Office of the Inspector General, OAI-12-88-01410 (May 1989)

[3]Mitchell JM, Sunshine JH; New England Journal of Medicine, 1992; 327:1497-1501

[4]"Conflicts of Interest: Physician Ownership of Medical Facilities," Council on Ethical and Judicial Affairs, American Medical Association, JAMA, May 6, 1992:2366-2369.

As early as 1986, the Institute of Medicine condemned physician self-referral in its examination on for-profit enterprise in health care. Describing the patients' vulnerability in health care decision making, Brock and Buchanon[5] state that patients are especially vulnerable for two reasons: first, they lack the special knowledge required to judge the necessity of the recommended or provided service; second, the presence of illness or injury may make it difficult for the patient to engage in the type of self-protective bargaining behavior typically expressed in the admonition "caveat emptor," or "let the buyer beware." The report stressed that "Only if one believes that medical training renders physicians impervious to the effects of economic incentives or that patients can adequately cope with physicians' conflicts of interest can one be indifferent to economic conflicts of interests resulting from physicians' investments."

In December 1992, after considerable debate, the AMA voted to declare self-referral unethical, with a few exceptions. One year earlier, the AMA's Council on Ethical and Judicial Affairs had concluded that physicians should not refer patients to a health care facility outside their office at which they do not directly provide services when they have an investment interest in the facility. Exceptions are allowed if there is a demonstrated need in the community and alternative financing is not available. The Council stated that physicians have a special fiduciary responsibility to their patients and that "there are some activities involving their patients that physicians should avoid whether or not there is evidence of abuse."

SELF-REFERRAL AND MANAGED CARE

Prohibitions on self-referrals were created in the context of a traditional fee-for-service system, where there are no incentives for providers to control utilization. In a managed care arrangement that uses capitated payments, the implications of self-referral practices change considerably. It is highly unlikely that physicians who are receiving a capitated payment would actually refer for unnecessary services.

Accordingly, there is an exception for prepaid health plans under Medicare, including risk- and cost-based Medicare contractors. Therefore, we do not see these provisions as an impediment to the development of legitimate Medicare managed care arrangements.

LEGISLATIVE HISTORY AND SUMMARY OF LAW

Prohibitions on physician self-referrals were first enacted in the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), when Congress amended Title XVIII of the Social Security Act to prohibit the referral of Medicare patients to clinical laboratories by physicians who have a financial relationship with those laboratories (or whose immediate family members have such a relationship), unless they qualified for one of the many exceptions.

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[5]Brock D, Buchanon A, "Ethics of For-Profit Health Care," For-Profit Enterprise in Health Care, Gray BH, ed., National Academy Press, 1986.

The law has subsequently been modified in every piece of major Medicare legislation that has passed since its creation: OBRA 90, OBRA 93, and the Social Security Act Amendments of 1994 (SSAA 94). OBRA 90 and SSAA 94 included technical corrections and other changes, while OBRA 93 expanded the scope of the law by adding a list of ten additional designated health services, expanding and clarifying the exceptions, and applying certain aspects of the law to referrals for Medicaid services.

Health care reform deliberations during the 103rd Congress also re-evaluated the self-referral provisions. Proposals to create different exceptions, modify the list of covered services and even extend the self-referral provisions to all payers were among the changes that were considered in various bills.

Because of its exceptions, the current law **is** complicated. However, the essence of the prohibition is clear: If a physician or a family member has a financial relationship with an entity that furnishes items or services on the list, then he or she cannot refer Medicare or Medicaid patients to that entity. Unlike the anti-kickback statute, the law is triggered by the mere fact that a financial relationship exists; the intention of the referring physician is not taken into consideration.

The provisions state that the relationship may be through an ownership or investment interest or a compensation arrangement. The ownership or investment interest may be through debt, equity or other means, or an interest in an entity that holds such an interest; the compensation arrangement is defined as any remuneration that does not fit within certain narrow exceptions between the physician (or immediate family member) and the entity. OBRA 89 provisions became effective for referrals occurring on or after January 1, 1992; many of the OBRA 93 provisions that applied to the exceptions for clinical labs were retroactive to January 1, 1992. OBRA 93 provisions that apply to referrals for designated health services became effective January 1, 1995.

Following is the list of designated health services that are covered under the self-referral ban:

-clinical laboratory services;
-physical therapy services;
-occupational therapy services;
-radiology services (including MRI, CAT scans and ultrasound);
-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 prescriptions drugs; and
-inpatient and outpatient hospital services.

Although some inappropriate utilization may exist, Congress created a number of exceptions in recognition of existing business practices. While the Secretary has authority under Section 1877 to create new exceptions, we must first determine, and

specify in regulations, that any new exception will not pose a risk of program or patient abuse.

The in-office ancillary services exception is perhaps the most important exception. It exempts physicians (both group practices and solo practitioners) with ownership and/or compensation arrangements from the self-referral ban for most services provided in their offices if they meet a set of requirements. There are 14 additional exceptions, including ones for prepaid health plans, rural providers, and isolated financial transactions.

The statute also prohibits an entity from billing Medicare, Medicaid, the beneficiary or anyone else for a designated health service resulting from a prohibited referral. Under the Medicaid program, the Federal government cannot pay Federal financial participation to a State for medical assistance that is furnished as the result of a referral that would be prohibited under Medicare, if Medicare covered the service in the same way as the State Medicaid program. If a person collects any amount for services billed in violation of the law, he or she must make a timely refund. A person can be subject to civil money penalties or exclusion from Medicare, Medicaid and other programs if that person: (1) presents or causes to be presented a claim to any payer for a service that the person knows or should know is a result of a prohibited referral, or (2) fails to make a timely refund. The maximum penalty is $15,000 for each service.

If a physician or entity enters into a circumvention scheme (such as a cross-referral arrangement), which the physician knows or should know has a principal purpose of assuring referrals to a particular entity that would be prohibited if made directly, the participating providers could be subject to civil money penalties of not more than $100,000 for each scheme and exclusion from Medicare, Medicaid and other programs.

As of October 1994, 27 states have enacted legislation that restricts or qualifies self-referral. There is great variation among the states. Some only require disclosure of the financial relationship to the patient, while others prohibit such referrals.

REGULATIONS

We are faced with twin challenges as we try to implement this law. While the basic concept is simple, the legislative process created complicated exceptions. Adequately defining these exceptions has proven to be a daunting task. The resulting issues have played an important role in the development of the accompanying regulations. In addition, the repeated modifications to the underlying legislation that I mentioned earlier have further delayed and complicated the development of the implementing regulations.

Due to the order in which they were enacted and in which work began on them, we are issuing two separate rules: one for the provisions that are related to referrals for clinical lab services and one for the provision of the designated health services.

The proposed rule for the original legislation was published in the Spring of 1992. We received more than 300 comments on the proposed rule, many of which included multiple, technical questions and each of which needed to be addressed in detail. These comments included descriptions of practical considerations that we needed to weigh in order to achieve an appropriate balance.

In addition, we have spent a significant amount of time meeting with and talking to individual providers, their attorneys and industry associations in an attempt to deal fairly and proactively with issues that are raised by the law and subject to interpretation in the regulations. Many of these discussions have focused on reviewing individual situations that do not fit clearly within one of the stated exceptions, but which have the same or similar situations as those that are provided for in the exceptions.

The final rule for the self-referral provisions for clinical lab services is under review and we hope to be able to publish it shortly.

The final rule on referrals to clinical laboratories will contain many definitions and interpretations that will also apply to referrals for all designated health services. As a result, we expect the rule to answer many questions for situations that are prohibited under the law as it is currently written. In addition, conversations with the provider community have also addressed questions relating to the interpretation of the OBRA 93 expansion; these outreach efforts have helped us prepare for the development of the second set of regulations. Once the first final rule is published, we hope to publish a proposed rule for the remaining provisions that are related to the designated health services within a few months. At this point, we estimate that we will publish the proposed rule for these provisions by the end of Summer.

ENFORCEMENT

As I am sure you know, the provider community is concerned about enforcement. We do not have discretion to alter the effective dates and, while we recognize that the complexity of the law raises many questions about how it is to be applied, it is nonetheless in effect. We feel that the spirit of the law is clear: physicians who want to continue to refer patients to entities with which they have financial relationships must fit within one of the exceptions. We intend to implement the law using the least burdensome manner that will still allow for effective enforcement. As we stated in a summary that we sent to provider groups, Medicare carriers and fiscal intermediaries, and other interested groups in January, we will begin compliance audits once the final rule for clinical laboratories is published. In addition, we will investigate reported abuses.

CONCLUSION

Appropriate referral guidelines are necessary to preserve the integrity of the programs that we oversee. While the basic concept of a self-referral prohibition is simple, the various statutory exceptions are complex, and in some cases difficult to interpret. Because the self-referral ban does not apply within the context of Medicare managed care, we do not believe that these provisions hamper the development of managed care in the Medicare program. As I mentioned earlier, we are in the process of implementing a cost-effective effort to combat fraud and abuse in the Medicare and Medicaid programs. Provisions limiting self-referral are, and should remain, an integral part of that effort.

Chairman THOMAS. Mrs. Johnson.

Mrs. JOHNSON of Connecticut. Thank you, Mr. Chairman. Thank you, Ms. Buto, for your testimony. Certainly Congress' role in the development of law in this area has not made it easy for HCFA to develop regulations, and I appreciate the time and effort that you have put in to listen to and respond to real world people out there affected by this law.

My questions are going to go to my belief that managed care is a form of delivering health care services that is in the process of evolving. I personally believe that physician-developed networks that give physicians more voice are going to be a better answer than some of the other networks developed by institutions or business organizations. But this law has slowed the evolution of physician-developed networks. That concerns me very much.

For instance, current law provides an exception for physician ownership and referral to the extent that the physician's relationship is with a federally qualified HMO. Now, of course, we have to do that.

What happens and how do your regulations address a State-qualified plan, and then how does it deal with not an HMO relationship, but a managed care relationship, and in your experience, because at this point you probably have more experience than anyone in the whole room, having talked to a lot of these people, what do you think will be the impact of your regulations on the ability of physicians to develop independent networks that then could negotiate with insurance companies or hospitals or other elements in the system to assure physician-voiced integrated care delivery systems?

Ms. BUTO. Let me start with that question and see if I can address the other questions that you have raised. We, too, as you know, are looking at trying to provide more choices for Medicare beneficiaries, more managed care opportunities along with fee for service. In looking at the rule, certainly one of our key concerns was the impact on the development of managed care entities and integrated delivery systems.

The law has a number of provisions. In past years amendments we have specifically seen changes that will allow for greater flexibility for these kinds of arrangements. Let me give you an example. The personal services provision that was added recently in OBRA 1993 recognizes many of the relationships that are evolving between group practices or other physician practices under an integrated delivery system.

Similarly recognized the recruitment provisions have the kinds of recruitment that occur in these systems. The ownership provisions in the group practice area have essentially been modified to recognize the many arrangements group practices engage in as part of these systems.

One comment about managed care in relation to these provisions—Managed care is many things, as you well know. It can range anywhere from a fee-for-service discounted managed care arrangement where under the law, the incentives are still there in some sense to fully capitated systems beyond federally qualified HMOs where there may be very little chance or no chance of abuse under this law.

The law provides for an exception that allows us to look at arrangements where there is no possibility of patient or program abuse, and we are particularly looking at these kind of bundled payment arrangements where the incentive would be entirely different.

Mrs. JOHNSON of Connecticut. Since my time has expired, could I ask you to provide me with some documentation. I do not want you to write a whole new report, but there must be memos and things you share with each other that show how changes in the current law have tried to respond to the needs of integrated delivery systems.

Ms. BUTO. We would be glad to do that.

[The following was subsequently received:]

Before OBRA 1993, it did appear that the self-referral provisions might hamper the development of integrated delivery systems (IDSs) and coordinated care arrangements. However, changes were made in OBRA 1993 to accommodate and address these concerns. Beyond the broad exception for capitated plans, following are some of the additional exceptions to the self-referral prohibition the address issues raised by the facilities and physicians involved in IDSs. Please note that each exception has specific requirements, which are set in statute, that must be met in order for the physicians and/or facilities to quality for the exception.

Exception for physician ownership interests in hospitals. This exception allows physicians to refer to hospitals in which they have an ownership interest if the investment is in the entire hospital and not a specific unit.

Exception for payments to employee. This exception allows physicians who are employed by a facility to refer to the facility.

Exception for physician recruitment. This exception allows facilities to pay physicians to relocate to a geographic area without prohibiting the physician from referring to the facility.

Exception for "isolated transactions." This exception allows an entity to purchase a physician practice (either solo practitioner or group practice) and not have the transaction count as a financial relationship that would prohibit referrals.

Exceptions for the leasing of office space and the leasing of equipment. This exception allows physicians to refer to the entity from which they lease office space or equipment, despite having a financial relationship with the entity.

Finally, it appears that IDS arrangements often include group practices that are organized by the IDS's hospital(s). To accommodate this, the definition of group practice takes into consideration the financial relationships of hospitals and group practices by not requiring that group practices be controlled or organized by physicians.

Mrs. JOHNSON of Connecticut. What other problems do you see that have not yet been addressed, and specifically I want to know what kinds of changes have to be made in the law and how you would advise making them so that we do not prejudice the physician-operated systems on the issue of capitated and noncapitated payments.

I am not sure. I think our society's experience with capitated payments is problematical. Capitated payments have resulted in underfunding in some systems and certainly have driven adverse behavior. I do not want the Federal law to take a stand on capitation versus noncapitation, bundling versus nonbundling. I think some of the managed care structures that are more flexible than that are going to prove to also provide better quality care.

If you could help me look at what are the current impediments to those more flexible care systems and what in your experience could be done to open the law to those, I would appreciate it very much. Thank you very much.

Ms. BUTO. I would be glad to do that.

[The following was subsequently received:]

As you know, there are many forms of IDSs, and the business arrangements associated with them continue to evolve and change. The law already contains broad exceptions for capitated entities under Medicare, potentially similar broad exceptions should apply under Medicaid. For entities doing business in an noncapitated environment, the exceptions already provided in the law address a wide variety of situations. given that IDSs can function in both environments, we believe that the law is neutral in regard to capitation versus fee-for-service. As a develop regulations that implement the expansion of the self-referral provisions beyond lab services, we intend to examine each service to try to prevent harm to bona fide, nonabusive arrangements operation in the both capitated and fee-for-service environments.

Chairman THOMAS. Mr. Stark.

Mr. STARK. Thank you, Mr. Chairman. Miss Buto, you mentioned that we can expect the final regulations on the first self-referral law, which was enacted in December 1989, shortly?

Ms. BUTO. Shortly. We are sending them to——

Mr. STARK. Could you tell me in a little more detail when those——

Ms. BUTO. What shortly is?

Mr. STARK. Yes.

Ms. BUTO. They have cleared HHS. In essence, they are going over later this week to the Office of Management and Budget. I do not know if this is the right time to mention it, but I do want to add that we have been enforcing those provisions, which we do think are fairly clear in the law.

Mr. STARK. I understand that. But I am sure that there are a lot of seminars waiting to be organized around these regulations. What do you think OMB will do? Sit on them, move them quickly, what is your best guess?

Ms. BUTO. I cannot predict, but we have already been over to provide some background briefing and hope to help walk them through it as soon as they get it.

Mr. STARK. I might ask the Chair if he would consider joining with me in writing to OMB to ask them, now that HCFA has finished the regulations on the first law, to speed up their process. Then we can see what kind of problem we face, and I would ask if we might all on the Subcommittee push this along, whatever the regulations, people may not like, but the devil we know is perhaps somewhat better than the devil we do not.

Chairman THOMAS. If the Member is asking me to joust with the bureaucracy, I am more than willing to join in.

Mr. STARK. Mrs. Johnson covered another question on the issue of how as we move into managed care, we do not completely eliminate it unless basically there is capitation, one would presume there is an elimination there of incentive from between—as between procedures and referrals.

Are you now assessing or studying any of the billing procedures or payment structures in new types of managed care? I guess in Medicare, you see it in Medicaid fairly often, but in Medicare it would be only under say the Medicare Select type arrangement. Are you looking at what is happening in that area at all—is there any formal study?

Ms. BUTO. We have not done a formal study, but we have made ourselves available, to managed care organizations, hospital organizations that are interested in PHO-type arrangements, and the group practice organizations which represent a variety of different

arrangements in order to fully understand what is going on, what arrangements are under way now.

Mr. STARK. Are you prepared or do you think you will be prepared to recommend to us any changes that you feel are needed legislatively. When do you think you might do that?

Ms. BUTO. We will certainly look at it and want to work, I think, collaboratively with the Committee to look at further changes that are necessary.

Mr. STARK. You think there will be some?

Ms. BUTO. Possibly. I have to say in the regulations we have really bent over backward to try to again do what we can to accommodate evolving arrangements. We will look at them.

Mr. STARK. Thank you. Thank you, Mr. Chairman.

Chairman THOMAS. Certainly. Does Mr. McCrery wish to inquire?

Mr. MCCRERY. Thank you, Mr. Chairman. Ms. Buto, let's talk about indirect and direct relationships in the context of self-referral. As we know, some indirect relationships can be rather tenuous, and I am wondering if you can give us any idea this morning how you plan to define indirect relationships so that this law is not carried to rather absurd extremes.

Ms. BUTO. When you say indirect relationships are you talking about the family relationships or the indirect financial relationships?

Mr. MCCRERY. Indirect financial relationships.

Ms. BUTO. We have really tried to stay closely to the intent and the spirit of both just the ownership and compensation-related items along with the exceptions so that our definitions, while we try to be flexible about recognizing arrangements that fall under the exceptions, stick very closely to the exceptions laid out in the statute.

We are proposing a few additional exceptions where we think there are not any real possibilities of abuse. In terms of the indirectness or directness, I think the statute is clear on what—the tests of relationships or if fair market value is involved in an exchange, or if there is a contract, and so forth. The relationship must be constructed in such a way that it is considered to meet the requirements.

Mr. MCCRERY. So, you are sensitive to this issue of indirect relationships and you are trying to make sure that you do not apply the law in such a way that it really becomes absurd?

Ms. BUTO. One thing I think I mentioned earlier is the integrated delivery systems. They represent a much broader umbrella and we are looking at whether there are issues Which impede the development of bona fide integrated delivery systems. That must be balanced against the concern about inappropriate utilization resulting from the ownership interests. It is not an easy issue. These are complicated arrangements, as you know.

Mr. MCCRERY. Yes. I just have one more question. It is kind of a fun question. I have been told that this example is correct, but I want you to think about it and tell me if it is. I am told that an orthopedist cannot rent or sell a wheelchair or crutches to a patient that he has treated, with the effect in some cases being that the patient goes to the doctor and gets treated, and then would have

to be literally carried to a pharmacy or a medical equipment place to buy the crutches or wheelchair. Is that correct?

Ms. BUTO. That is correct. The statute providing DME by the physician's office is not permissible. I should add that one thing we have not looked at is whether that makes a difference in the amounts that are paid for DME. That would be something to look at in addition to the issue of utilization.

Mr. MCCRERY. Thank you.

Chairman THOMAS. Mr. Kleczka will inquire.

Mr. KLECZKA. Thank you, Mr. Chairman. I just have two real quick concerns. Ms. Buto, one of the criticisms of the law is the reporting requirements that physicians are going to have to go through. Could you tell the Committee in some detail what exactly will be required of physicians?

Ms. BUTO. For reporting?

Mr. KLECZKA. For reporting.

Ms. BUTO. We are concerned about that, too. There was some initial reporting not by physicians, but by the clinical labs back in 1991. We did a survey. We are looking at an unburdensome way for physicians to certify that they are in compliance with the provisions that is not burdensome does not require micromanagement of every financial arrangement.

Mr. KLECZKA. So, you are saying the actual reporting requirements have not been developed yet?

Ms. BUTO. For the new provisions, no. We have already gotten the clinical lab provisions through a survey of the labs themselves to see what physicians-owners are associated with the labs. For new provisions the question is how do you go about doing it. We would like to look at a nonburdensome way to survey physicians or certify them.

Mr. KLECZKA. One of the other criticisms I have heard, which I personally do not believe is that under this law a doctor providing a patient with sample medication free of charge would be prohibited.

Ms. BUTO. Say that again, I am sorry, sample medication?

Mr. KLECZKA. Dispensing sample medication free of charge to a patient would be prohibited.

Ms. BUTO. I do not believe so. If I am wrong, we could—as long as there is no billing involved I do not think there is an issue.

Mr. KLECZKA. That is one of the things that has also surfaced. Thank you, Mr. Chairman.

Chairman THOMAS. Mr. Christensen will inquire.

Mr. CHRISTENSEN. Ms. Buto, just for a moment here, let's have a little conversation on common sense. I know it is hard to come by at HCFA and government bureaucracies, but, following the line of questioning that Mr. McCrery had, does not it seem a little bit odd that an orthopedist could not provide crutches or a wheelchair for that patient as he was leaving the office. Would not that be a logical extension of his services to provide that patient with the needed equipment to get around?

Ms. BUTO. On the one hand it might make sense. On the other hand there are many medical equipment suppliers who deliver to the home, who have a variety of different choices of wheelchairs

and crutches. The physician may not have, even if he kept an inventory, the item that the patient needs.

We have actually many suppliers, and they operate pretty efficiently to get equipment to the patient. So, on the one hand, yes, it sounds logical. On the other hand, it may not meet the patient's need exactly.

Mr. CHRISTENSEN. Who do you think knows best? Who would know better about what is going to fit that patient's needs, the orthopedist or some medical equipment supplier?

Ms. BUTO. The orthopedist will know what fits the need, but whether the orthopedist is going to keep a huge inventory that is required to meet a variety of needs, I think, is questionable.

Mr. CHRISTENSEN. I am a whole lot more suspect of the Federal Government telling people what they need rather than an orthopedist. I would trust the orthopedist a whole lot more.

Ms. BUTO. I do not think the Federal Government wants to tell patients what kind of wheelchairs or crutches they need. The law is pretty clear on that point, but I just want to make the point that there are other ways to get the items to people.

Mr. CHRISTENSEN. In your response to Mrs. Johnson, you mentioned the exception on prepaid plans, but the exception is limited to traditional HMOs. Do you see in your discretionary authority establishing other exceptions as we begin looking at integrated delivery systems and other HMOs?

Ms. BUTO. Again, we think that integrated delivery systems can be pure fee-for-service billing, not under any sort of managed care arrangement. They can be under an overall umbrella ownership, but really be a series of fee-for-service entities billing. I do not think the incentive changes under the Stark law. If we identify situations which are not covered by exceptions where we clearly think there is no possibility of abuse, we are going to look at that and see if we can create an exception. So, yes.

Mr. CHRISTENSEN. Thank you.

Chairman THOMAS. No further questions. Ms. Buto, rather than take the time of the Subcommittee, I have just a few questions that I want to offer to you so that you can respond to them in writing for us to get a little more comfortable framework for the physician self-referral law prior to issuing the regulations.

As you might guess, these are some of the specific concerns as expressed by my colleague from Wisconsin. I would not want to try to put a timeframe on the response, simply to say as soon as practicable we would appreciate a response.

Ms. BUTO. We will try to get them back to you quickly.

Chairman THOMAS. For those that need more detail than others, if you could just give us the indication that they need more detail and that would be appreciated. Without any further questions, we want to thank you. We know you are anxious to get back to work. Thank you.

Ms. BUTO. Thank you very much. Get the regulations out.

Chairman THOMAS. I did not want to add that. If I could ask our next panel, Dr. Bristow, Gail Warden, chairman of the board of trustees of the American Hospital Association; Frederick Wenzel, Dr. Balfour, Phil Griffin.

I want to thank all of you in advance. If you have any written testimony it will be made a part of the record without objection, and you may begin to inform us in any way that you feel we need to be informed, and we will begin with Dr. Bristow, then just move across the panel, if you might.

Dr. Bristow, thank you for joining us.

STATEMENT OF LONNIE R. BRISTOW, M.D., PRESIDENT-ELECT, AMERICAN MEDICAL ASSOCIATION

Dr. BRISTOW. Thank you very much, Mr. Chairman and Members of the Subcommittee. My name is Lonnie R. Bristow. I am a practicing internist in San Pablo, California, and the president-elect of the American Medical Association.

Chairman THOMAS. Dr. Bristow, if I might, which will serve warning to the others, these mikes are very, very unidirectional. You have to speak directly into it and relatively up close so that everyone will be able to hear your remarks. Thank you.

Dr. BRISTOW. Thank you. My remarks today will focus on the AMA's position on physician ownership and referral issues, and our recommendations for changes in the current self-referral law.

As you know, both self-referral laws, known as Stark I and Stark II, are now in effect and are being enforced, yet the Health Care Financing Administration has not published a final rule on the implementation of the provisions of Stark I. HCFA has not yet published a notice of proposed rulemaking that sets forth the specific policies of Stark II. However, the Office of Inspector General at the Department of Health and Human Services has already published a final rule with a comment period that sets forth sanctions. Somehow it appears that the cart has gotten before the horse.

Last December the AMA, along with AHA, ASIM, and other medical specialty societies and health groups asked HHS to declare a moratorium on sanctions until final rules implementing the Stark II legislation are published.

HHS denied our request. Yet, any misunderstanding regarding when the law applies or whether an exception exists could lead to the imposition of significant penalties on physicians. Further confusion was added by the Ninth Circuit Court's recent decision in the *Hanlester* case in which the court strongly disagreed with the IG's interpretation of the self-referral law.

We urge the Subcommittee to consider a moratorium until regulatory guidance is finalized.

The AMA has been a leader in developing reasonable restrictions on the practice of physician self-referral. In 1991 the AMA's Council on Ethical and Judicial Affairs took a strong position on this issue, building on work that began in 1986 on conflict of interest.

In general, the AMA's ethical policy is that physicians should not refer patients to a health care facility at which they do not directly provide patient care or services when they have an investment interest in that facility. However, physicians may refer their patients to facilities in which they have an ownership interest if the physician directly provides care or services.

Physicians should be able to invest in and refer patients to an outside facility whether or not they provide direct care or services

at that facility if there is a demonstrated need in the community and alternative financing is not available.

Need might exist when there is no facility, when there is an inadequate number of facilities of reasonable quality in the community or when use of existing facilities is onerous for our patients. If this community need exception is met, the physician should also comply with the further ethical requirements. Investing and referring as a direct extension of a physician's commitment to serve patients' needs is ethical and also desirable. We urge inclusion of a community need exception to the law.

At this time, I would like to highlight further recommendations that the AMA considers to be important. First, we urge you to amend the law to add an exception to allow the legitimate use of shared office facilities by physicians. Without it, access to appropriate care for patients will be negatively impacted.

Physicians often share clinical labs, x-ray machines, and other in-office diagnostic equipment with physicians in their office building so that they can provide their patients with on-site health services. Without this exemption, physicians who share a common office laboratory would be forced to set up two labs in order to treat their individual patients. The alternative of closing the lab, sending possibly critically ill patients to an outside lab for lab work and forcing them to return to their physicians' offices for their treatment is simply counterproductive to effective, efficient care.

Second, we support a specific exception to the law for referrals made by nephrologists for services relating to renal dialysis.

Third, it is not clear if injectable drugs administered in a physician's office are included in the self-referral ban or if the ban is limited to oral drugs. As one example, physicians are unsure if oncologists are prohibited from administering chemotherapy in their offices. We urge that outpatient prescription drugs be deleted from the list of designated health services, or at the very least, that this provision of the law be clarified.

Fourth, we urge deletion of the site of service requirements that govern where in-office ancillary services must be furnished. The location where the services are provided has nothing to do with improper utilization.

Finally, we believe that blanket prohibitions are not appropriate nor necessary. Instead, we strongly support the use of physician profiling to first identify and then address any utilization concerns by the comparison of practice patterns. We also ask that HHS focus its efforts on those activities or entities that are thought to be troublesome.

In conclusion, Mr. Chairman, we have urged caution in drafting legislation that attempts to govern ethical issues, and we would like to underscore, however, that patient benefit and patient access to health care facilities must be the primary concern, and our goals are similar.

We are most appreciative of the efforts of Chairman Thomas and the Subcommittee to improve and clarify provisions of the self-referral statute that are unclear, unnecessary, and unduly regulatory, and we look forward to continued work with you on these important issues.

[The prepared statement follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Committee on Ways and Means
Subcommittee on Health
U.S. House of Representatives

RE: Physician Ownership and Referral

Presented by Lonnie R. Bristow, MD

May 3, 1995

Mr. Chairman and Members of the Subcommittee:

My name is Lonnie R. Bristow, MD. On behalf of the American Medical Association (AMA), I appreciate the opportunity to testify before you this morning. I am a practicing internist in San Pablo, California and am President-elect of the AMA. The AMA commends your examination of the important issues relating to the physician ownership of medical facilities and the referral of our patients to these facilities. My remarks today will discuss the AMA's position on physician ownership and referral issues and our recommendations for changes to the current self-referral law.

BACKGROUND

The original ban on physician self-referral, known as the Stark I law, was enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989. The statute, with limited exceptions, prohibits a physician from referring Medicare patients to clinical laboratories in which the physician -- or an immediate member of the physician's family -- has a financial interest. The Stark law was enacted in response to a study conducted by the General Accounting Office (GAO) in Florida that found that physicians who had an investment or passive ownership interest in an outside laboratory ordered more tests than physicians who had no tie with the laboratory. The implication of the report was that physicians ordered unnecessary tests to assure the financial success of the venture. This theory was never proven, and the GAO report was sharply criticized for failing to examine whether or not the ordered tests were medically necessary. The Stark I law took effect on January 1, 1992.

This self-referral ban was expanded by OBRA 1993 and modified by the Social Security Act Amendments of 1994 to prohibit physicians from referring Medicare and Medicaid patients to additional entities for the furnishing of designated health services, including physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging (MRIs), computerized axial tomography (CAT) scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment; 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. This expansion of the law, known as Stark II, became effective on January 1, 1995.

Although both self-referral laws are now in effect and are being enforced, HCFA has not published a final rule on the implementation of the provisions of Stark I nor has HCFA published a Notice of Proposed Rulemaking that sets forth the specific policies of Stark II. It should be noted, however, that the Office of Inspector General at the Department of Health and Human Services published a final rule on March 31, 1995 with a comment period that sets forth the civil money penalty, assessment, and exclusion provisions that will be imposed for violation of Stark II.

There are a number of areas where the law is unclear and where physicians need appropriate guidance from HCFA so that they can be certain that they are in compliance with the provisions contained in Stark I and II. The AMA, along with several medical specialty societies and key health groups, asked the Department to declare a moratorium on sanctions until final rules implementing the Stark II legislation are published. The Stark II law is extremely complex, and any misunderstanding regarding when the law applies or whether an exception exists could lead to the imposition of significant penalties on physicians. Since the adoption of the OBRA 1993 self-referral provisions, physicians and their advisors have spent thousands of hours scrutinizing every word of legislative history and statutory language to determine whether the law applies to their financial relationships. Further confusion was added by the Ninth Circuit's recent decision in the Hanlester case, in which the court strongly disagreed with the Inspector General's interpretation of the self-referral law.

The Department denied our request for a moratorium on January 26, 1995, stating in written correspondence that a moratorium could not be granted because the Department lacks the legal authority to specify another date for the duties imposed and the sanctions specified in the statute. The Department also stated that self-referral practices generate significant costs to the Medicare and Medicaid programs and that any delay would have budgetary costs. Last, the Department noted in its letter that "we are sympathetic to the need for further advice and guidance on the more subtle aspects of the statute." In light of the complicated issues raised by the legislation as written, we urge this subcommittee to consider a moratorium until such time as regulatory guidance is finalized.

AMA POSITION ON PHYSICIAN OWNERSHIP AND REFERRAL

The AMA was a leader in developing reasonable restrictions on the practice of physician self-referral. In 1991, the AMA's Council on Ethical and Judicial Affairs took a strong position on this issue. While physician investment in health care facilities can provide important benefits for patient care, a potential conflict of interest exists when physicians refer patients to facilities in which they have an ownership interest. Therefore, in general, the AMA's ethical policy is that physicians should not refer patients to a health care facility outside their practices at which they do not directly provide patient care or services when they have an investment interest in the facility. **However, physicians may refer their patients to facilities in which they have an ownership interest if the physician directly provides care or services.** For example, a referral to an ambulatory surgical center by the surgeon performing the surgery should be allowed.

There are other situations where self-referral is appropriate and necessary in order to properly serve our patients' needs. Physicians should be able to invest in and refer patients to an outside facility, whether or not they provide direct care or services at the facility, if there is a demonstrated need in the community for the facility and alternative financing is not available. Need might exist when there is no facility, when there is an inadequate number of facilities of reasonable quality in the community, or when use of existing facilities is onerous for our patients. For example, the use of an existing facility could create a hardship for patients if the facility is so heavily used that patients would face undue delays in receiving health care services. There would also be a hardship if patients had long travel times that made receiving care difficult, especially if patients needed to use the facility regularly.

There may be situations in which a needed facility would not exist if referring physicians were prohibited from investing in the facility. The burden on the developer of a particular facility would be to show that adequate capital could not be raised without turning to self-referring physicians after undertaking efforts to secure alternative financing, such as acquiring funding from banks and other financial institutions. If this community need exception is met, the physician should comply with further ethical requirements relating to the marketing efforts of the facility, referral requirements, return on investment, noncompetition clauses, disclosure of investment interests to patients, and utilization review. Physicians are often exclusively motivated by the important needs of their patients in becoming involved in these arrangements. Investing and referring as a direct extension of a physician's commitment to serve patients' needs is ethical and desirable.

RECOMMENDATIONS FOR LEGISLATIVE MODIFICATIONS TO STARK I AND II

The AMA has been pleased to participate in a coalition of medical specialty societies, the Medical Group Management Association, and other health groups to develop proposed legislative changes that would improve and clarify the current law. Following are key proposals that the AMA considers to be important and which are included in the coalition's recommendations.

Shared Facilities

The current law contains a general exception to the ban on physician referrals for the provision of in-office ancillary services. However, the law does not include an exception for in-office facilities shared by physicians. We urge you to amend the law to add an exception to allow the legitimate use of shared office facilities by physicians. With the help of many Members of this Subcommittee, the Ways and Means Committee included a shared facility exception in the health system reform bill reported out of Committee in 1994. Solo practitioners and small physician groups often have sensible agreements with other physicians to share office space and equipment in order to reduce costs and to benefit their patients. For example, physicians often share clinical laboratories, x-ray machines, and other in-office diagnostic equipment with other physicians in their office building so that they can provide their patients with on-site health services, such as EKGs and ultrasounds. These practical arrangements allow physicians to save money and resources by sharing the overhead for a common clinical laboratory or x-ray machine rather than setting up duplicate facilities in the same office building.

Patient access to appropriate treatment will be impacted if an exemption for shared facilities is not implemented. For example, physicians who share a common office laboratory would be forced to set up two laboratories in order to treat their individual patients. The alternative -- closing the laboratory, sending critically ill patients to an outside lab for blood work and forcing them to return to their physicians' offices for treatment -- is counterproductive to effective care.

Community Need

As mentioned above in the discussion on the AMA's ethical policy on physician ownership and self-referral, the AMA strongly supports an exception to the self-referral prohibition if there is a demonstrated need in the community -- for example, the absence of adequate alternative facilities -- and alternative financing is not available. The AMA urges inclusion of a community need exception to the self-referral law to allow a facility owned by referring physicians to exist in an urban or rural community where there is a community need and no other financial support for the facility exists. Many areas such as inner city communities and small towns have problems similar to rural areas in attracting non-physician investors for needed health care facilities. There may be situations in which a needed facility would not be built if referring physicians were prohibited from investing in the facility. Furthermore, need might exist when there is no facility of reasonable quality in the community or when use of existing facilities is onerous for patients.

Referrals Made By Nephrologists

We support a specific exception to the law for referrals made by nephrologists for services relating to renal dialysis. Nephrologists commonly contract with hospitals to provide dialysis to hospital inpatients at facilities owned by nephrologists. Pursuant to the self-referral statute, which includes "inpatient and outpatient hospital services" on the list of designated health services, it appears that nephrologists would not be able to treat their dialysis patients at their own dialysis units. Furthermore, we have received a number of inquiries from physicians asking for clarification of the term "inpatient and outpatient hospital services." As you are well aware, the Ways and Means Committee included an exception for nephrologists in the health system reform bill reported out of Committee in 1994.

Outpatient Prescription Drugs

Outpatient prescription drugs are included on the list of designated health services contained in the self-referral statute. It is not clear if injectable drugs administered in a physician's office are included in the ban, or if the ban is limited to oral drugs. Physicians are unsure if oncologists are prohibited from administering chemotherapy in their offices and if nephrologists are forbidden from dispensing in-office prescription drugs to their renal dialysis patients. We urge that outpatient prescription drugs be deleted from the list of designated health services, or at the very least, that this provision of the law be clarified.

In-office Ancillary Services

We urge modification to the current law in-office ancillary services exception to the prohibition of certain referrals. The exception presently contains unnecessary restrictions that should be deleted on the provision of durable medical equipment and parenteral and enteral nutrition services by physicians and group practices. Such restrictions diminish the quality of care and interfere with physicians' ability to care for patients.

Furthermore, we urge deletion of the requirements that the in-office ancillary services "must be furnished in a building in which the referring physician furnishes physician services unrelated to the furnishing of designated health services, or in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice for the provision of some or all of the group's clinical laboratory services, or for the centralized provision of the group's designated health services (other than clinical laboratory services), unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse..." Ancillary services provided by physicians are part of a continuum of care that physicians provide for their patients whether a patient is in the physician's office, is hospitalized, or has been discharged to another facility or to his or her home.

We also ask that the supervision component of the in-office ancillary services exception be clarified. The current law exception describes designated health services 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 directly supervised by the physician or by another physician in the group practice..." We urge inclusion of language that changes the "direct supervision" concept to "general supervision" to clarify that nurses, technologists, technicians, and other non-physician personnel are capable of providing ancillary services to patients under the general supervision of physicians without the need for direct physician supervision in connection with each and every test or procedure.

Reporting Requirements

The self-referral statute contains a provision that requires that entities providing covered items or services for which payment is made shall provide information to the Department of Health and Human Services Secretary regarding the entity's ownership arrangements. We urge repeal of this section. Physicians are already burdened with complying with numerous regulatory requirements under CLIA, OSHA, and Medicare and should not have to spend additional time away from caring for their patients in order to provide this data. It is also not apparent how the Department of Health and Human Services intends to use this general information regarding ownership; HHS should instead focus efforts on entities thought to be problematic.

Group Practices

The current law definition of a group practice includes a physician compensation requirement that provides that no physician who is a member of a group can directly or indirectly receive compensation based on the volume or value of referrals by the physician. The law also provides that "a physician in a group practice may be paid a share of overall profits of the

group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician". We urge deletion of these provisions. We have received numerous questions and comments from physicians who oppose these provisions and do not understand why the law is written in such a way that the government is unnecessarily intrusive into the internal financial arrangements and operations of their private practices.

Designated Health Services

We urge deletion of the following items or services from the list of designated health services to which the self-referral prohibition applies: physical therapy services; occupational therapy services; radiation therapy services and supplies; prosthetics, orthotics, and prosthetic devices and supplies; outpatient prescription drugs; and inpatient hospital services. We would also clarify the definition of radiology or other diagnostic services, as well as outpatient services.

CONCLUSION

We have urged caution in the past in drafting legislation that attempts to govern the ethical issues related to physician ownership of health care facilities and referral of patients to these facilities. We are most appreciative of the efforts of Chairman Thomas and the Subcommittee to improve and clarify provisions of the self-referral statute that are unclear, unnecessary, and unduly regulatory. We would like to underscore that patient benefit and patient access to health care facilities must be of primary concern. We look forward to continued work with the Chairman and the Subcommittee on Health on these important issues.

Chairman THOMAS. Thank you.
Mr. Warden.

STATEMENT OF GAIL WARDEN, PRESIDENT, HENRY FORD HEALTH SYSTEM, DETROIT, MI AND; CHAIRMAN, BOARD OF TRUSTEES, AMERICAN HOSPITAL ASSOCIATION

Mr. WARDEN. Thank you, Mr. Chairman. I am Gail Warden, president of the Henry Ford Health System in Detroit and chairman of the board of trustees of the American Hospital Association. On behalf of our 4,600 institutional members who are hospitals and health systems, we are pleased to have an opportunity to talk with you today about self-referral prohibitions in section 1877 of the Social Security law.

I would like to make three points to begin with. First, the pace of change in health care makes it necessary to take another look at the self-referral law. Second, at a minimum, a moratorium for the time being should be placed on the enforcement of the law, and, third, we have some recommendations to make the law more relevant to today's health care systems.

I think you are all aware from the previous testimony and discussion that health care is undergoing a transformation like no other in history—moving away from a traditional method of paying individuals, physicians, hospitals and others for each service and treatment to one, in many cases, where the risk for utilization and cost is being borne by the hospital and the physicians instead of the insurance company.

It is moving to a more integrated approach, in which groups of providers are organized in a myriad of arrangements and paid a set fee to provide a comprehensive set of services for each enrollee. As that occurs, there is an incentive to focus on prevention and to provide appropriate services.

In all of these arrangements, of which there are many, cooperation is the key ingredient in these coordinated care systems. Ownership, employment, or exclusive contracts are not always an option, and so what is happening is that physicians and institutions try to do their best to respond to a changing marketplace, and end up with a blend of different kinds of arrangements.

In our own case we have a group practice. We also have IPA networks with community hospitals that are not part of our system. We have spot purchasing for certain tertiary care services to try to keep the cost down, and a number of other kinds of arrangements.

We believe that the guiding principles in the Stark law—which were to prevent inappropriate referrals based on the potential for financial gain—remain valid. However, at the same time, with the dramatic changes that have taken place in the delivery system, where there have been significant structural changes in the methods of payment and the business relationships between providers, we feel that the progress is being impeded by the law, and despite the encouraging comments this morning about the fact that there were ways to seek exceptions, I think we have to recognize that these changes are taking place so rapidly that once you have determined what the exception might be, a new kind of arrangement probably has been created to respond to a different thing that is happening in the competitive marketplace.

So, with that in mind, we feel that there is a need to revisit the law, particularly those elements of the law that prevent new systems from evolving. We feel there is a need to delay enforcement of the law until such time as some of these issues can be examined.

As the Chairman has said on another occasion, it is not just a challenge. It is impossible in many cases to try to stay within the law and at the same time do what you think is right. One of the considerations, I think, is that the law does provide for exceptions for what it calls pure models of managed care.

At this point, I am not sure there is a pure model. Even Kaiser, which was the original pure model, has departed from that and has a lot of different kinds of arrangements in different marketplaces. We also believe that the consideration of the changes should not occur in a vacuum and we should recognize that there are a number of other laws in place to address these issues, such as the anti-kickback law, Federal laws regulating conduct of tax exempt organizations, and so on.

Our recommendations are that we add an exception for certain risk-sharing arrangements, many of which can be enumerated if you want to talk about them; that there be an exception for ownership in integrated delivery systems, which are, in fact, structured in such a way that they are concerned both about cost and quality; and that there be an amendment to the list of designated health services, particularly as it relates to inpatient and outpatient hospital services because DRGs regulate inpatient care and in doing so control utilization. We also would suggest the establishment of an advisory opinion mechanism that includes a requirement that HHS issue advisory options under certain conditions.

In conclusion, our feeling is that we particularly think we need to look at integrated networks and the impact that this law is having upon them, and what kinds of options might be created for exceptions. We look forward to working with you to try to do that.

[The prepared statement follows:]

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Statement
of the
American Hospital Association
before the
Subcommittee on Health
of the
Committee on Ways and Means
of the
United States House of Representatives
on
Self-referral Provisions in the Social Security Act

May 3, 1995

Mr. Chairman, I am Gail Warden, president of the Henry Ford Health System in Detroit and chairman of the board of trustees of the American Hospital Association (AHA). On behalf of AHA's 4,600 institutional and 50,000 individual members, I am pleased to be here to discuss self-referral prohibitions in Section 1877 ("Stark I and II") of the Social Security Act.

INTRODUCTION

Health care delivery in this nation is undergoing a transformation like no other in history. We are rapidly moving away from the traditional ways of delivering care -- namely, paying individual physicians, hospitals and others for each service and treatment they provide -- in favor of a more coordinated, integrated approach. This new approach includes groups of providers paid a set fee for each person enrolled in their network, with an incentive to focus on prevention and providing appropriate services. In other words, cooperation is a vital ingredient in the coordinated care systems that are making health care delivery more efficient and cost-effective. Avoiding the delivery of unnecessary care is another. These new systems reflect AHA's vision for the future: community-based, collaborative networks of providers focused not just on treating illness and injury, but also on improving the overall health status of their communities.

RE-EXAMINING SELF-REFERRAL LAW

In light of this relatively new focus on cooperation, it has become necessary to reexamine the underlying concerns that led to the initial passage of Representative Pete Stark's (D-CA) legislation and amendments broadening the self-referral ban. And it is absolutely necessary to raise questions about the ability of providers to intelligently comply with a statute that is as broad and complicated as the self-referral law, and carries with it such significant sanctions for noncompliance.

The guiding principle for the Stark law -- to prevent physicians from inappropriately referring patients based on the potential for financial gain -- remains valid. This law, however, was drafted when the health care delivery system was dramatically different from the systems that are evolving today in communities across the nation. Since the law was enacted, significant structural changes have occurred in methods of payment and in business relationships between providers. Networks of providers are working together to respond to community health needs and payer expectations.

As hospitals, doctors and other providers develop alternatives to the fragmented fee-for-service model of health care delivery, Congress should consider that such progress could be severely impeded by a law created at a different time, for a different system, and for relationships that are becoming less prevalent.

The AHA shares the concern that only necessary care should be provided to patients. To do otherwise can create risks to people's health and drain scarce dollars from the health care

system. When the system is subjected to fraud and excessive utilization, the AHA expects and encourages rigorous enforcement to follow. We believe, however, that there are significant problems with the law as written.

REVIEW SELF-REFERRAL LAW, DELAY ENFORCEMENT

As Chairman Thomas has noted, there are two key issues to be addressed. First, there needs to be careful examination of the effects of the self-referral law on the development of new, more efficient delivery systems, and elements of the law that prevent new systems from evolving must be stricken or amended. Payment mechanisms that align incentives among providers and create disincentives to the provision of excess services are becoming commonplace. In an environment in which providers are fully or partially accepting risk for excessive utilization through capitation arrangements, withholds, incentive pools, and other methods designed to encourage appropriate and cost-effective care, the need for such sweeping legislation is questionable.

Second, a delay in enforcement of the law is needed. No final regulations have yet been issued for Stark I, a law passed in 1989 that prohibits physician referrals for only clinical laboratory services where certain financial interests exist. As for Stark II -- which in 1993 broadly expanded the list of services covered -- not even proposed regulations have been published. Yet, the Stark II provisions went into effect on January 1, 1995. There is universal agreement that the statute, as amended, is extremely difficult to interpret and apply. Without the benefit of implementing regulations, compliance with the ban, as the chairman has said, "isn't just a challenge, it's almost impossible." Considering that a violation of the law carries a potential civil penalty of up to $15,000 per claim and possible exclusion from the Medicare and Medicaid programs, a delay in enforcement is strongly urged.

In December 1994, AHA and 11 other provider organizations wrote a letter to relevant federal agencies expressing this concern and requesting a moratorium on the effective date. The response from the Department of Health and Human Services (HHS) Inspector General and the Administrator of the Health Care Financing Administration was that they lacked statutory authority. Without arguing the legal scope of their authority, there is no question that Congress does have the power to delay enforcement until regulations are drafted, subjected to public comment, and published.

We should not rush to fully implement a law that, as written, could undermine positive developments in the health care market.

REGULATION ALREADY EXISTS

Consideration of changes to Stark I and II should not occur in a vacuum. The confusion that providers face in applying the Stark law to a specific referral arrangement is exacerbated by the fact that the same arrangement is generally regulated by several other federal and state laws as well. These arrangements, which usually involve hospitals, are subject to scrutiny under the anti-kickback law, federal tax law regulating the conduct of tax-exempt organizations, state referral bans, and the corporate practice of medicine prohibition -- to name a few.

Yet another federal law that regulates fraudulent and abusive activity is the federal False Claims Act. Most recently, this act has been used to characterize billing errors as false claims subject to civil and criminal sanctions. This approach to enforcement undermines the collaborative relationship that should exist between the government and providers if we are to efficiently process the millions of transactions that occur in health care every year. The AHA supports the government's goal of preventing true fraud, but we are concerned about the consequences of painting too many billing problems with too broad an accusatory brush.

We must consider, as the chairman has noted, whether the Stark law is needed in light of the tools already available to the government to monitor and punish those who abuse or defraud the system. We suggest that the current enforcement apparatus is more than adequate to address these issues.

The proliferation of overlapping, but often inconsistent, laws is not only confusing but unfair, unwieldy, and inefficient in a time of dwindling resources. This Congress has the opportunity to simplify an unnecessarily complex federal approach to health care fraud and abuse.

AHA'S RECOMMENDATIONS

The following are recommendations for fundamental revisions to the current structure of the law, in order to make it more relevant and workable.

Add an exception for certain risk-sharing arrangements.

Currently, Stark II contains a general exception for a limited number of prepaid health plans that are federally qualified. Multi-provider networks utilize various risk-sharing arrangements to discourage excessive utilization. There is not a big difference between these emerging arrangements and federally qualified prepaid plans, in terms of creating a disincentive to provide unnecessary services. Accordingly, we recommend amending the law to include an exception for certain risk-sharing arrangements, such as those that place the provider of services at full or partial financial risk for the cost or utilization of those services through withholds, capitation, incentive pooling, per diem payment arrangements, or other methods.

Add an exception for ownership in integrated delivery systems.

While there is no single commonly accepted definition of an integrated delivery system, the health care field has evolved to a point where several types of structures are commonly adopted to help providers work together to serve patients. For example, physicians may own or invest in a management services organization (MSO), preferred provider organization (PPO), physician-hospital organization (PHO), physician-hospital arrangement (PHA), or similar organization designed to coordinate the delivery of health care services. The referring physician may be managed by, or contract with, the organization and have an ownership or investment interest in the organization itself, and not merely in a part of the organization. The Stark law should expand the current exception for physician ownership in a hospital to include ownership in integrated delivery systems. This would remove one barrier to hospitals and physicians joining together to create coordinated care systems.

Amend the list of designated health services.

Stark II contains a long list of designated health services for which referrals may be prohibited. The breadth of such a list is questionable and should be limited to services where objective studies have convincingly demonstrated overutilization by referring physicians with a financial interest in an entity.

At a minimum, the apparent catch-all designated health service called "inpatient and outpatient hospital services" should be deleted. The inclusion of this broad category of services is incomprehensible within the context of Section 1877 and adds no precision to the law's attempt to target specific health services that may be candidates for overutilization. Virtually every inpatient and outpatient service involves some form of financial relationship with physicians who may need to refer patients, making the Stark law a mechanism to restrict all health care delivery.

Establish an advisory opinion mechanism.

AHA strongly recommends amending Section 1877 to include a mandatory advisory opinion mechanism. We commend Chairman Thomas for introducing legislation (H.R. 1234) that includes provisions requiring HHS to issue advisory opinions under certain conditions. Such a mechanism is necessary given the practical problems Section 1877 presents for providers attempting to operate more efficiently, the interpretive problems that have accompanied rapid changes in health care, and the fact that a violation of Section 1877 does not require proof that a referral was made with improper intent.

Other considerations

A review of the Stark law should also consider whether a "financial relationship" should be defined to include compensation arrangements, in addition to ownership and investment interests. The law appears to apply to every legal method of exchanging consideration between physicians (and their immediate family members) and an entity, thereby requiring

exceptions for every form of appropriate financial relationship.[1] It generally prohibits a referral for services if the referring physician has any compensation arrangement with the entity to which the patient is referred.

The multi-provider networks of care that are organizing across the country rely on close coordination of a variety of health care services to yield increased efficiencies. Such close coordination makes necessary a variety of compensation arrangements between providers. With network incentives geared toward the conservation of resources, risk of overutilization is curtailed.

Congress may also wish to consider that the effect of the Stark law can be to create an uneven playing field among providers, and a disincentive for providers to work together. For example, under the current law, referring physicians may not be part of a joint venture with a hospital to develop a new hospital unit, but those referring physicians can create a loosely defined group practice to offer the same services on their own. This places one group of providers -- hospitals -- at a competitive disadvantage, and most importantly, presents a barrier to hospitals and physicians uniting to provide services.

In addition, a number of ambiguities in the statute should be clarified to conform with the rapid diminishment of fee-for-service payments and the related risk of overutilization. For example, the current exception for physician recruitment arrangements applies only to recruiting physicians to a new location, such as a new city or state, but not for recruiting physicians to a different practice in the same area or system. If providers are to serve local community needs in an efficient manner, this narrow exception should be revisited.

Other exceptions, such as the current exception for personal service agreements, should permit various incentive payments that are not dependent on the volume or value of referrals. Newer payment methodologies that require providers to accept and share risk, and do not encourage overutilization, have features that were not contemplated when Section 1877 was developed. Also, certain ambiguous definitions need to be cleared up, such as "referral" and "fair market value." In addition, we would be happy to discuss various technical changes that could improve the law.

CONCLUSION

Mr. Chairman, individual practitioners and independent hospitals cannot create coordinated delivery systems overnight. We must remain open to a variety of arrangements that involve varying degrees of ownership, control, and risk as health care delivery systems emerge that are responsible for everything from prenatal services to long-term care, providing needed services to an enrolled population within a defined amount of resources, and customer satisfaction.

While the self-referral provisions are designed to stop abuse and overutilization, they also inhibit providers' ability to respond to market demands for integration that provides higher quality, cost-effective, and readily accessible health care. Clarifying and repealing parts of the law are necessary to encourage the creation of delivery systems that can respond to these demands. We are sympathetic to the concerns that Congress has about abuses in the health care system. Indeed, we share those concerns. But the law must not be allowed to penalize providers that are trying to respond to modern demands for integrated, cost-efficient care. We look forward to working with you to keep that from happening.

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[1] Structurally, Stark adopts a broad prohibition on certain physician referrals and permits exceptions. Under this structure, the intent of the parties is irrelevant, whereas under the anti-kickback provisions of the Fraud and Abuse Statute, the intent to induce referrals is critical. Stark is easiest to understand as an "exceptions bill" and, in that regard, is similar to section 61 (a) of the Internal Revenue Code [26 U.S.C. § 61(a) (1988 & Supp. III 1991)]. That Section defines gross income as "all income from whatever source derived" unless there is a deduction or an exclusion from gross income. Once the structure and scope of the Stark prohibition are understood, the exceptions become critical.

Chairman THOMAS. Thank you very much, Mr. Warden.
Mr. Wenzel.

STATEMENT OF FREDERICK J. WENZEL, EXECUTIVE DIRECTOR, MEDICAL GROUP MANAGEMENT ASSOCIATION, ENGLEWOOD, CO

Mr. WENZEL. Thank you, Mr. Chairman. I am Frederick Wenzel, executive director of the Medical Group Management Association in Englewood, Colorado. We appreciate the Committee's interest in exploring changes to the physician self-referral law.

While our goal is not to condemn the basic intent of the law, which was designed to curtail abusive investment and referral behavior, we have identified a number of serious problems with the statute and would like to recommend a number of changes to the Committee.

The written testimony, which was made available to the Committee, expands on my remarks. It includes conclusions from our analysis of the statute and its effects on physician practices and a discussion of specific problems with the law, and a series of recommended changes.

No single piece of recent legislation, including the Medicare fee schedule, CLIA, Clinical Lab Improvement Act and OSHA, Occupational Safety and Health Act, has as this law has complicated the lives of our physicians and our practices. While MGMA supported the original physician self-referral legislation enacted in 1989, subsequent amendments to the law in OBRA 1993 transformed it into a regulatory nightmare.

What was once a reasonable regulation of physician joint ventures has now become government micromanagement of physician practices and unnecessary intrusion into an emerging competitive market for health care services. The law is sufficiently ambiguous to defy implementation and the HCFA, as we heard earlier, has been of little help providing guidance on even simple issues.

For example, the law prohibits referral to an entity in which a physician's immediate family member has an investment. Yet, family member has not been defined.

Physician practices are prohibited from providing durable medical equipment to their patients. However, the HCFA carriers have not provided clarification on how a practice is to distinguish prosthetics, orthotics, and supplies from DME. The law ostensibly applies only to designated services and only to Medicare and Medicaid, but the key definitions of referral and group practice suggest broad applicability.

Many of the provisions are simply unnecessary. For example, what purpose is served by prohibiting a physician practice from having a practice site which provides only physical therapy services or mammography screening? In many instances practices have limited space to provide full range of service at one location.

Furthermore, satellite locations can offer a measure of patient convenience and access. Stark II restricts physician practices from opening satellite facilities unless they also provide unrelated physician services at that site, even if such services are provided better elsewhere. Many other provisions are counterproductive.

The Stark law prohibits physician ownership in certain services, such as radiation therapy, prosthetics and orthotics. These services are unlikely candidates for utilization. In fact, a case can be made that patient compliance rates for these services are the real issue and poor compliance may result in greater cost to the government programs in the long term.

The self-referral law both directly and indirectly restricts physician participation in managed care networks, and as we heard earlier, it is limited to federally qualified HMOs, and nowadays one wonders why you would want to be federally qualified anyway, and here we exclude, of course, State arrangements, IPAs and other kinds of networks.

In these arrangements, physicians are in most cases only partially at risk or capitated, may have a financial relationship with more than one network, and may even have some fee for service. Many of these arrangements could violate at least one provision of the Stark II restrictions.

The Stark law uses definitions that add additional burdensome regulatory requirements. The most glaring are physician compensation requirements included in the definition of group practice.

For example, it is impossible to apply the compensation test in Stark II fairly and uniformly across physician employees and tax exempt clinics or medical schools, physician employees of for-profit groups, physician owners who are also employees, physicians in single specialty practices, and physicians in multispecialty practices, all of whom are treated somewhat differently.

Contrary to what the defenders of the law may allege, adoption of the recommendations detailed in my written statement would hardly open the door to major opportunities for physician abuse of the Medicare and Medicare Programs. In fact, a streamlined self-referral law could actually be implemented by HCFA, and that would really make things a lot simpler for them and for us as well.

We want to thank you very much for your consideration of these issues which are very important to our group practices. We represent nearly 7,000 group practices throughout the country, and believe me, we have heard from just about every one of them on Stark I and Stark II.

Thank you, Mr. Chairman.

[The prepared statement follows:]

TESTIMONY OF FREDERICK J. WENZEL, FACMPE
MEDICAL GROUP MANAGEMENT ASSOCIATION

My name is Frederick J. Wenzel, FACMPE. On behalf of the Medical Group Management Association (MGMA) and its 6,500 physician group practice members, I would like to thank you for the opportunity to appear before you this morning. I am both the Executive Director and Chief Executive Officer of MGMA, and an advisor to the President of the Marshfield Clinic in Marshfield, Wisconsin, where I served as Executive Director for almost twenty years. Marshfield is a large multi-speciality clinic which serves a largely rural population. We greatly appreciate both the Chairman's and Committee's interest in exploring changes to the so-called physician self-referral law. It is not MGMA's goal to condemn the basic intent of the law to curtail abusive investment and referral behavior, but we have identified a number of serious problems with the statute. My comments are designed to examine these problems and recommend possible solutions for them to the Committee.

No single piece of recent legislation has been as disruptive to medical group practices as has this law, including the implementation of the Medicare fee schedule, CLIA, and OSHA. While MGMA supported the original physician self-referral legislation enacted in 1989, the subsequent amendments to the law in OBRA '93 transformed it into a regulatory nightmare. What once was reasonable regulation of physician joint ventures has now become government micro-management of physician practices, and unnecessary intrusion into the emerging competitive market for health care services.

Founded in 1926, the Medical Group Management Association is the oldest and largest association representing medical group practices. Our members include over 6,500 groups of every size, description, and geographical location. They include most world renowned multispecialty clinics, all of the nation's academic practice plans, and thousands of smaller single and multi-specialty practices. Altogether MGMA member groups provide practice settings for over 130,000 physicians -- about two-thirds of all physicians in group practice in the United States. MGMA is affiliated with two other organizations: The Center for Research on Ambulatory Health Care Administration ("CRACHA"), the research arm of MGMA, and the American College of Medical Practice Executives ("ACMPE"), an organization that makes professional credentialling available to individual practice administrators.

Overview

The collapse of government-directed health care reform in the 103rd Congress sent a loud message across the country to providers, purchasers, and patients. It is now clear that the federal government is not going to assume responsibility for the management of private sector health care financing and delivery. MGMA supports this outcome, and believes that the market will sort itself out, even if it means a certain amount of pain for providers in general, and many of our members in particular. In light of the encouragement that the new 104th Congress is now giving to market competition and in particular managed care, we think that it is appropriate that the Congress explore existing laws that may impede the larger goal of this Committee's leadership to further market competition, instead of government regulation. So, we are very pleased and grateful that the Committee has decided to undertake a thorough review of the self-referral law.

For the better part of the past year MGMA has been part of a work group comprised of the American Medical Association, the American Dental Association, the American Society of Internal Medicine, the American Society of Clinical Oncology, and several representatives from managed care organizations. This group has worked tirelessly to try to make sense of the self-referral law, including work on the so-called "Stark III" amendments

debated in 1994. Together the group represents a broad cross-section of providers and payers who are engaged in the evaluation of the emerging competitive markets. In addition, we have consulted with literally hundreds of health lawyers and accountants, and thousands of medical group practices about the problems they face complying with the self referral law. Based on these experiences we have drawn several conclusions that serve as the bases for our recommended changes to the law. These are:

1. The law is sufficiently ambiguous to defy implementation, and the Health Care Financing Administration ("HCFA") has been of little or no help providing guidance on even the simplest issues, even though Stark I has been in effect since 1992 and Stark II became effective January 1, 1995. For example, the law prohibits referral to any entity in which a physician's family member has an investment -- yet family member has not been defined. Physician practices are prohibited from providing durable medical equipment to their patients -- however, HCFA carriers have provided no clarification as to how a practice is to distinguish prosthetics, orthotics, and supplies from DME. The law ostensibly applies only to designated services and only to Medicare and Medicaid -- but the key definitions of "referral" and "group practice" suggest broader applicability

2. Many of the provisions are simply unnecessary. For example, what purpose is served by prohibiting a physician practice from having a practice site which provides only physical therapy services? In many instances, practices have limited space to provide a full range of services at one location, and furthermore, satellite locations offer a measure of patient convenience and access. Stark II restricts physician practices from opening satellite facilities unless they also provide "unrelated" physician services at the site, even if such services are better provided elsewhere.

3. Many other provisions are counter productive. The Stark law prohibits physician ownership in certain services such as radiation therapy and prosthetics and orthotics. These services are unlikely candidates for overutilization. In fact, a case can be made that patient compliance rates for these services are the real issue, and poor compliance may result in greater costs to government programs in the long term. Restricting physician ownership of these services is more likely to reflect competing financial interests, rather than concern about Medicare and Medicaid program abuse. We hope that the Committee will not permit special economic interests to dominate the market. Rather, a full range of competition should be encouraged including competition from and among physician practices. The Stark law currently favors nonphysician suppliers over physician group practices, and certain physician specialities over others.

4. Finally, the self-referral law both directly and indirectly restricts physician participation in managed care networks. The law does provide a limited exemption for federally qualified HMOs, but not state qualified ones. Furthermore, most of the emerging products are not HMOs but rather IPAs and other network arrangements. In these arrangements, physicians are in most cases only partially at risk or capitated, may have a financial relationship with more than one network, and may have some fee-for-service revenue. Many of these arrangements may violate at least one of the Stark II restrictions.

The original Stark I law was an appropriate legislative response to abuses, some real, and some potential, arising from joint ventures between commercial clinical laboratories and joint venture partners who were frequently referring physicians. In some of these arrangements, physician investors put up very little money, and provided little or no medical direction or other professional contribution to the venture, yet had significant potential for return if the investors ordered a sufficient volume of lab tests. In other words, the investment returns were thinly disguised kickbacks in return for the physician's continued or promised referral of business to the laboratory. While the worst of these schemes were already subject to prosecution under the Medicare and Medicaid anti-kickback statute found

in Section 1128B(b) of the Social Security Act, Congress perceived at the time, and with some reason, that the anti-kickback law was too difficult to invoke, and too subject to the ambiguities of individual judicial precedents, to effectively deter the behavior of concern to the Congress. Because the underlying rational for Stark I was to prevent abusive joint ventures, the law logically included a number of workable exceptions to ensure that legitimate physician office, hospital, and other laboratory services were not disrupted and patient access and cost were not compromised.

Unfortunately, before the Health Care Financing Administration could implement the Stark I law, the law was greatly expanded through amendments included in the Omnibus Budget Reconciliation Act of 1993. The law, as amended, is now commonly referred to as "Stark II." There are two major differences between the Stark I and II laws:

- Stark II expands the list of designated health care services, to which the self-referral prohibition applies, beyond clinical laboratories to encompass the majority of therapeutic and diagnostic services covered by the Medicare and Medicaid programs. These include some services for which there has been no demonstrable record of abuse related to physician ownership, and others where there is not even a significant potential problem or which may have the unattended consequence of producing the opposite effect -- the underutilization of service;

- Stark II also moved the focus away from the original concern about abusive joint ventures, by adding numerous and detailed provisions governing the internal operations of physician group practices, hospitals, medical schools, and other entities that employ or contract with practicing physicians.

The effect of these two major changes has been to convert a sound and workable law into an over-reaching, complex, and intrusive example of federal micro-management within the health delivery system. Proof of Stark II's complexity can be found in HCFA's inability to develop even proposed implementing regulations for Stark II almost two years after its enactment, and several months after it became effective and legally enforceable. Further evidence can be marshaled by talking to physicians, hospital administrators, practice administrators, and health lawyers who have tried to understand the law and apply it to even relatively routine physician employment and contracting situations within their practices and institutions. Finally, the author of the legislation has himself admitted that the legislation produced results that he had not intended.

Problem Statement

Following are some of the real world problems being encountered by those trying to understand and comply with the Stark II law. These are organized to correspond with the different types of exceptions as they appear in the statute.

1. General Exceptions to the Prohibition on Physician Ownership And/Or Compensation Relationships

   - The "in-office" ancillary exception in Stark II is overly prescriptive in terms of the site of service. There is no policy rationale for telling physician practices how many diagnostic and therapeutic service sites they should be permitted to develop for the convenience of patients, or how ancillary services and physician services should be delivered in combination. Similarly, an ownership and referral law should not dictate the degree of physician supervision necessary to maximize effective utilization of non-physician personnel, as long as physicians remain legally responsible for the ancillary services provided by non-physician personnel, and the services are billed by physicians or bona fide group practices.

- Stark II has also undercut the in-office ancillary exception by prohibiting physician practices from providing durable medical equipment ("DME") and parenteral and enteral services. Thus, an orthopod can cast a broken leg, but cannot dispense a crutch as the patient leaves the office. An oncologist can prepare a patient for a bone marrow transplant procedure, but can not give the same patient the nutritional supplements necessary to build up the patient's strength during the pre-operative phase. Certain antibiotic therapy can be delivered in connection with a physician's services, but nutritional supplements that might utilize the same pump and tubing must be provided by an outside entity. In many cases physicians are required to send injured or severely ill patients to other providers at different practice sites, significantly increasing the time, effort and cost that these patients must endure when receiving needed care.

- The general exception available for ancillary services delivered in connection with prepaid, at risk plans is too narrow to accommodate today's dynamic marketplace. Limiting the exception to federally qualified health maintenance organizations and Medicare contractors applies concepts of the 1970's and 1980's to the marketplace of the mid-90's. Groups that enroll Medicare or Medicaid patients on a pre-paid at risk basis, and are licensed or otherwise regulated under state law offer the same disincentives to overutilization as would a federal risk contractor, (and probably more than a Medicare cost contractor), but only the latter qualify for the Stark II managed care exception.

- Stark II provides an exception for physician ownership in rural areas, but not for physician compensation arrangements with entities providing care in rural areas. This seems a distinction without a difference. Similarly, just as physician investment may be necessary to bring ancillary services into under-served rural areas, so too should it be available in under-served urban areas. Also, the definition of a rural area is not in all cases workable. A county is designated as rural or urban in its entirety, without regard to its size or diversity. So a county, often in the western United States, may be designated as urban because it has one metropolitan area within its boundaries, while the remainder of the vast county, stretching, in some cases for hundreds of miles, is completely rural.

- Stark II fails to recognize the similarities between ancillary facilities shared by solo physicians operating at the same physical location, and fully integrated practices. Just as bona fide group practices are easily distinguishable from abusive joint ventures, so too are cost effective shared service arrangements developed by physicians who are on site, involved in the supervision of non-physician personnel, and utilizing the shared facility as an adjunct to their own office practices for the convenience of patients.

2. Exceptions Related only to Ownership and Investment

- Stark II permits a physician to have an ownership interest in a hospital, as long as it is in the entire hospital and not some subdivision of it, and continue to refer patients to that hospital for designated services. On the other hand, the law currently prohibits physicians from doing exactly the same thing at other facilities such as nursing homes, hospices, surgery centers, dialysis facilities, rehabilitation facilities, which may provide a designated service incidental to the facility service. For example, if physician ownership of inpatient rehabilitation hospitals is not a problem under Stark, ownership in an outpatient rehabilitation facility ("CORF") should not be either. If physician ownership in an ambulatory surgery center and referral to it for surgery is acceptable, then the fact that an incidental lab service is

also provided should not poison the well.

3. Exceptions Related Only to Compensation Arrangements

Stark II provides a number of statutory exceptions to protect routine relationships between physicians and other entities to which they may refer patients for designated services. These relationships include office and equipment leases, management and service contracts, physician recruitment situations, and others. The problems in this area of the law are more technical than conceptual, but there are many inconsistencies which need to be clarified, and arbitrary requirements which can be removed. To take one example, the contracts exception requires that a physician have only one contract with an entity to which he/she refers. This sounds reasonable in the abstract when applied to a solo practitioner providing services as a medical director of an inpatient hospital unit, but when a group practice with 150 physicians sits on the same campus with the hospital, they may have dozens of relationships, and there is no purpose to be served to force all into a single contract form for a single term.

Some compensation exceptions are available for transactions between physicians and hospitals, but not physicians and other entities that provided designated services. As with the hospital ownership exception discussed above, these distinctions have no rational basis.

4. Reporting Provisions

Stark II gives HFCA more tools than it can usefully use to gather information on physician ownership. There is no need for HFCA to engage in any "fishing expeditions" through surveys or otherwise. The fact that after several years, HFCA has not developed a reporting instrument under Stark II illustrates that point. Completion of surveys represents a cost to medical practices, and based on a review of draft survey forms prepared by HCFA, the data would be expensive to obtain and tabulate, and of questionable use to the government.

5. Definitional Problems

- The Stark law uses definitions in the law to add additional burdensome regulatory requirements. The most glaring problems are in the physician compensation requirements included in the definition of "group practice." These have proven totally unworkable, even ignoring the question of whether the federal government has an appropriate role in telling physicians who choose to practice together in clinics how they may be compensated. For example, it is impossible to apply the compensation test in Stark II fairly and uniformly across physician employees in tax-exempt clinics or medical schools, physician employees of for-profit groups, physician owners who are also employees, physicians in single specialty practices and physicians in multi-specialty practices, all of whom are treated somewhat differently under the test. Meanwhile, solo practitioners are not even subject to the test.

- Similarly, the law's definition of "referral" has added tremendous confusion and complexity to the law since it is not limited to physician referrals for those services subject to the law's prohibitions by virtue of being "designated" health services.

- Finally, the definition of "designated health services" in Stark II was the technical manner of expanding the law's reach beyond clinical laboratory services to a whole host of other diagnostic and therapeutic items. Some of these services offer little or no opportunity for excessive utilization and referral abuse. They may in fact represent just the opposite -- the potential for underutilization which then results in

greater costs to the Medicare program because the patient's condition goes untreated, resulting in more costly care down the road. Included in this category are radiation therapy, prescription drugs, physical and occupational therapy, and prosthetic and orthotic services. Permitting physician investment and referral to entities providing such therapeutic services poses no threat to the financial integrity of the Medicare and Medicaid programs. In addition, by including hospital services in the definition of designated services, Stark II has invalidated physician/hospital joint ventures designed to provide cost efficient services to hospital inpatients. For many such services economies of scale do not justify a hospital maintaining its own in-house service; instead it is more economical for hospitals and physicians to share in the cost and operation of certain services used by both inpatients and ambulatory patients. Since hospitals are paid a fix amount by Medicare for each inpatient based on his/her diagnosis, there is little incentive to overutilize ancillary services.

- In reexaming the provisions of the self referral law we believe the test should be whether or not physician ownership in services has caused or could reasonably lead to over utilization; and whether or not a restrictive provision is designed to prevent program abuse, or is just one more effort by the federal government to micro-manage an economic market that is not in need of such management. Heaping restriction upon restriction should not be raised as an excuse by regulators not to use the ample authority already provided through the fraud and abuse statutes, and the original ownership and referral law. More rules cannot substitute for the enforcement of existing laws, particularly when rules as embodied in the Stark II provisions would favor some economic entities (non-physicians) over others. We believe that the recommended changes summarized below would preserve the original intent of the Stark law, but at the same time restore market equity and patient access to services.

Section-By-Section Recommendations

1. General Exceptions Covering Both Ownership and Compensation Arrangements

   - Eliminate the prohibition against physician practices providing DME and parenteral and enteral services within their own practices
   - Eliminate the "site of service" restriction on in-office services
   - Amend the physician supervision requirement applicable to non-physician personnel to clarify that direct supervision is not required, and substitute a general supervision requirement.
   - Expand the prepaid exception to include state regulated and Medicaid plans
   - Clarify the rural exception to provide for compensation arrangements as well as ownership interests.
   - Add a community need exception
   - Add a shared services exception

2. Exceptions Related Only to Ownership

   - Expand the exception for physician ownership in hospital facilities to include ownership in other facilities including surgery centers, hospices, nursing homes, dialysis facilities, and CORFS.

3. Exceptions Covering Compensation Arrangements

   - Clarify exceptions related to space rentals, equipment leases, and personal services contracts

- Revise the compensation test in the employment exception by eliminating the reference to "direct or indirect"
- Extend the exception for compensation paid by a hospital to a physician for services "unrelated to designated health services" to include compensation from any entity - not just hospitals.
- Extend the physician recruitment exception to include all entities, not just hospitals

4. Reporting Requirements

- Repeal the section

5. Definitions

- Eliminate the physician compensation restrictions from the group practice definition
- Remove from the list of designated services those services which are not subject to abuse, whether or not they involve physician ownership, including:
  - radiology (except for CAT and MRI)
  - radiation therapy
  - prosthetics and orthotics
  - occupational and physical therapy
  - outpatient prescription drugs
  - hospital outpatient services not involving other designated services
  - hospital inpatient services

- Limit the definition of a referral to a request for a service on the designated list.

6. Preemption

- Provide for a preemption of state laws governing physician ownership and referral.

A Streamlined Self-Referral Law

The above represents a compilation of significant problems associated with the Stark self-referral law. Amending the law to correct these problems will in no way lessen protection against physician ownership in and referral to those services which have the potential for over utilization and abuse. We should note that this is not a complete compilation of the problems associated with the Stark law. There are many other minor and technical issues that should be addressed if the Congress should choose to amend the law. However, this compilation points to the need for a thorough reexamination of Stark II.

Contrary to what defenders of Stark II may allege, adoption of the recommendations detailed above would hardly open the door to major opportunities for physician abuse of the Medicare and Medicaid programs. In fact, a streamlined self-referral law, which could actually be implemented by HCFA, would enhance the government's ability to identify and prosecute those blatant joint ventures at which the law was originally directed.

An amended law, while not overreaching like Stark II, would still be far broader than Stark I, covering those ventures like major imaging centers that might provide particularly strong financial incentives to referring investors, and those lower-cost items like DME where the Inspector General suspects that unscrupulous suppliers have been taking advantage of the government payers.

The government also retains its full arsenal of other enforcement tools, including:

- Criminal sanctions under the anti-kickback law;
- Civil sanctions for medically unnecessary services and services of substandard quality; and
- Routine claims review, denial, and recoupment of overpayments for medically unnecessary services.

States also have an important role to play through facility and personnel licensure and certification to ensure that all providers of diagnostic services meet acceptable levels of quality.

Finally, the private sector payers are constraining utilization of services both through capitated payment systems, and more vigorous gatekeepers, prior approval, practice protocols, utilization review, and quality assurance mechanisms. As more Medicare and Medicaid beneficiaries are enrolled in managed care organizations, those organizations will increasingly dictate how, where, and whether ancillary services are provided. In the long run, these market pressures will better protect the federal programs than will any federal intrusion in the organizational design of physician group practices and other providers.

Chairman THOMAS. Thank you, Mr. Wenzel.
Dr. Balfour.

STATEMENT OF DONALD C. BALFOUR III, M.D., PRESIDENT, AMERICAN GROUP PRACTICE ASSOCIATION, ALEXANDRIA, VA

Dr. BALFOUR. Mr. Chairman and Members of the Subcommittee, on behalf of American Group Practice Association, I want to thank you for this opportunity to comment on problems associated with compliance with the self-referral statute.

I am Dr. Donald C. Balfour, president of American Group Practice Association, president and medical director of the Sharp Rees-Stealy Medical Group in San Diego, California. For group practices and integrated systems of care, the physician ownership and self-referral statute breaks down primarily in the area of compensation arrangements. We believe that it was Congress' intent to promote systems of care which improve access to care, continuously improve the quality of services, and reduce costs.

These simultaneous objectives are best achieved through the clinical and financial integration of services. To promote these objectives, Congress must take steps to eliminate the uncertainty regarding interpretation of the referral statute. Barriers to integration such as the compensation provisions of the statute must be removed to allow such systems to align incentives with the objective of improving the health of communities.

The Stark legislation is complicated and in some instances contradictory. Consequently, the task of interpreting conflicting provisions in the statute perplexes many group practice leaders and other providers and appears to be equally baffling to HCFA. Such confusion, when combined with the threat of enforcement and stiff statutory penalties clearly chills the interest of group practices in offering designated health services, even when doing so is beneficial to patients.

Several exceptions to the referral and billing prohibitions are set forth in the Stark law. Qualification for one of the enumerated exceptions is required if Medicare and Medicaid referrals for designated health services are to be permitted. If the standards for each exception are not met, then the referral or billing may be viewed as a prohibited activity subject to all the attendant penalties, including exclusion from Medicare.

One of the most common exceptions accessed by physicians to permit billing by group practice is the in-office ancillary services exception. Stark II allows group practices to pay productivity bonuses to physicians based upon services personally furnished by the physician or furnished incident to such physician services so long as the share of bonus is not determined in any manner which is directly related to the volume or value of referrals by the physician.

It is unclear, however, the extent to which physician members of a group can receive compensation based on a percentage of revenue generated from ancillary services. It is extremely confusing that Congress expressly permits a bonus paid upon incident to ancillary services, but also restricts the group practice from offering a bonus which varies directly based on referrals for those services.

No exception to Stark exists for integrated health care delivery systems. Referrals between and among the components of integrated systems are in the best interests of patients. The integration of common services and facilities to avoid duplication and to conserve scarce resources is the cornerstone of such systems. We believe that the current referral law which does not recognize these systems of care impedes their ability to bring even greater efficiencies to the marketplace, and working with Congress and the administration the American Group Practice Association identified many areas of ambiguity in the current physician referral law.

These are enumerated in our written testimony. The AGPA's recommendations are to promote the quality, improve the access and reduce costs. Congress must take the following steps to eliminate the ambiguity and uncertainty regarding the interpretation of the physician ownership and self-referral statute.

The first point would be without clarification HCFA faces a great deal of uncertainty about the intent of the law and the meaning of significant terms, conditions, and exceptions in the statute. Absent clarification, we believe enforcement actions are unrealistic and improper. In the absence of further guidance from Congress, we recommend the postponement of the effective date of the statute for 2 years or until final implementing regulations are published.

The second recommendation is the continued evolution of the health care options which meet the needs of patients and payers is cause to rethink the policies underlying physician self-referral restrictions. At a minimum, statutory and regulatory initiatives should preserve the intent of the in-office ancillary service exception. The ability of group practices to engage in the delivery of health care services independently or as part of an integrated system of care depends upon this exception.

The final recommendation is both the antikickback law and the compensation provisions of the self-referral law seek to prohibit payments in exchange for referrals, and the associated potential for overutilization of services. It is unclear how the compensation aspect of the self-referral law provides any real benefit over the antikickback law.

In fact, its existence is having a negative effect of impairing legitimate marketplace transactions. Deleting the compensation provision while preserving the ownership provision would maintain the law's integrity and remove its detrimental effect on the market. American Group Practice Association recommends, therefore, that the physician referral statute be clarified, eliminating the compensation arrangement provisions. Thank you for the opportunity to share these observations. I will look forward to your questions and the opportunity to work with you on these issues.

[The prepared statement follows:]

Testimony to the
Subcommittee on Health
Committee on Ways and Means

Presented By

Donald C. Balfour III, M.D.

Re: Physician Ownership and Referral
May 3, 1995

Mr. Chairman and members of the Committee, on behalf of the American Group Practice Association, I want to thank you for this opportunity to comment on problems associated with compliance with the self-referral provisions of the Social Security Act.

I am Dr. Donald C. Balfour III, President of the American Group Practice Association ("AGPA"), President and Medical Director of the Sharp Rees-Stealy Medical Group in San Diego, California, and a practicing hematologist.

The AGPA represents multispecialty group practices that provide hospital and clinical services in integrated delivery systems. Medical group practices serve as the hub of many integrated delivery systems. A substantial and evolving body of research has shown that such systems of care are the highest quality and yet most cost effective providers of health services. Frequently, these organizations are the largest employer in a community. Some of our member groups provide services through a single point of service, some have large networks in a single region, and some have multiple sites in several regions and states. We believe that group practice should be encouraged as a means of improving access to and coordination of care, reducing the administrative costs of health care delivery, and monitoring both the quality and cost of health care services.

Federal self-referral legislation is intended to eliminate opportunities for over-utilization of health care services driven by economic incentives rather than by medical necessity. We join Congress in condemning unethical practices of physicians who abuse their patients' trust for personal financial gain. I ask however that you not lose sight of the simple truth that the vast majority of physicians do not fall into that category and most physicians continue to place their fiduciary duty to their patients above any personal concern.

For group practices and integrated systems of care, the physician ownership and self-referral statute breaks down primarily in the area of compensation arrangements. We believe that it was Congress' intent to promote systems of care which improve access to care, continuously improve the quality of services, and reduce costs. These simultaneous objectives are best achieved through the clinical and financial integration of services. The marketplace is demanding consolidated and integrated delivery system approaches in the transformation from fee-for-service to capitation and managed care.

To further promote these objectives Congress must take steps to eliminate the ambiguity and uncertainty regarding interpretation of the physician ownership and self-referral statute. Barriers to integration such as the compensation provisions of the statute must be removed to allow such systems to align incentives and rewards with the objective of insuring the health of enrolled populations.

Group practices are playing an integral role in a changing and evolving health care system, but we fear that some of the innovations of group practice medicine may be stifled by rigorous application of prohibitions set forth in the self-referral statute.

The emergence of integrated multispecialty group practices is a relatively recent trend in which the elements needed to provide all aspects of health care services to a population of people are brought together in a coordinated and accountable fashion. In such a system, the traditional paradigm of medical care shifts from the treatment of acute episodes of illness in individual patients to an emphasis on the continuous maintenance of the wellness of an enrolled population, and care provided at an appropriate level.

In direct response to market forces, small groups are now unifying into larger

multispecialty groups and groups are integrating with other health care entities, such as hospitals, ambulatory care facilities, and insurers. Currently, more than 30 percent of all physicians practice in group practices. Nationwide the number of group practices has nearly doubled from about 8500 in 1975 to about 16,500 in 1991. In 1975 there were about 67,000 group practice physicians, and by 1991 that number had nearly tripled to about 180,000.

Multispecialty group practices are patient-focused systems of care, which may be geographically decentralized with multiple convenient sites. Primary and specialty care is balanced to meet the needs of large groups, communities or populations. Sophisticated information management enables complete knowledge of health care expenditures, as well as systems to monitor utilization of services, measurement of cost and quality outcomes, patient satisfaction and access.

The ability to contain costs and maintain quality of care has attracted businesses seeking to control health insurance spending. Payers, especially those businesses that self-insure as well as those that have combined to create purchasing coalitions, are increasing their demands for efficient use of health care dollars because of the harsh effect of health care costs on their competitiveness. They want cost control and they want to buy care based on documented outcomes. They want consistent quality and processes across the system, and they don't want a health plan shortcut -- they want a real partnership with their providers. In short, they want VALUE.

Payers have also recognized one way to get value is to pay one organization for the complete spectrum of care -- primary, acute, rehabilitative and nursing care -- that their employees or enrollees need. A growing trend is for employers to contract directly with multispecialty group practices for their employees' health care, working in a collaborative manner to deliver effective and high quality patient care.

Group practice success in containing cost is achieved through the proper managing of patient care. Mayo Clinic's growth in spending per capita did not exceed GDP growth from 1988-92. At Henry Ford Health System's HMO, the capitation which physicians in the Henry Ford Medical Group receive to cover all professional services, inpatient care, ambulatory care and covered ancillary services has grown at an average rate of 7.15 percent between 1985 and 1993. This compares to an 9.95 percent annual growth rate in per capita national expenditures for comparable services. Henry Ford also has evidence that once efficient practice patterns are developed, there are verifiable carry-over cost benefits to fee-for-service populations served by the same physicians. For example, for services provided to the Medicare patient population, the annual increase in the average Medicare payment to Henry Ford Medical Group averages 4.5 percent since 1988, compared to a national average of 7.9 percent annual growth in Medicare costs.

Compensation Arrangements

The self-referral provisions are complex, highly detailed and, in spite of an exemption for group practice from aspects of the law, still cause numerous difficulties. For our membership, major confounding issues are introduced by the requirements related to compensation arrangements. An important aspect of what makes group practice medicine unique is the way our physicians are compensated. There are many methodologies for determining the income of physicians in groups. Traditional fee-for-service payment methodologies are giving way to salary structures coupled with profit sharing and incentives for physician characteristics that the group values, as well as capitation payment mechanisms that fluctuate with enrollment but align individual incentives with group objectives.

Examples of indicators which an organization might use to measure member performance include:

* Patient encounters, panel and nonpanel;
* Quality of care, measured by total of charts reviewed, percentage rated satisfactory or superior, and CME credits;
* Quality of service, measured through patient satisfaction ratings, patient complaints,

liability claims, compliments, office visits, new office visits, consultations, and complete physical exams;
* Cost effectiveness, measured by primary care physician panel activity, total cost of external referrals, ancillary service usage, and length of stay in acute or SNF facilities;
*Organizational participation measured by staff, department, or committee meetings, CQI/guideline meetings, hospital and specialty society meetings;
* Contributions to medical education; and,
* Research activities.

Because of the inherent differences between fee-for-service and capitated systems, the challenge to an organization comes as it merges data from the opposing revenue sources. Patients come to group practices under a mix of payment arrangements including fee-for-service, negotiated and direct contracting, and capitation. Most physicians and caregivers in such an organization are completely ignorant of the mechanism by which any patient's care is reimbursed. Once the efficiencies of capitation are realized among clinicians in the group, the mindset which results is heavily biased towards patient and care management.

We raise these issues because: 1) we believe in a market-based health care delivery system that enhances consumer choice and access to health care services, and promotes innovation; 2) we believe that delivery systems should compete for clientele on the basis of cost and quality; and 3) the dynamics of market competition are driven by strategies which accelerate the process of clinical and financial integration within an organization.

Barriers to Compliance

AGPA has included an issue brief on the status of the self-referral statute and regulations as an attachment to this testimony. Without belaboring the details of the construction of the statute or the evolution and delay of the regulations, I would like to share our view of the difficulties and obstacles we face in attempting to comply with the prohibitions which became effective in 1992, and subsequently, for designated health services (DHS), which became effective January 1, 1995.

AGPA has actively participated in the legislative and administrative work on this statute since it was first introduced as the "Ethics in Patient Referrals Statute of 1988." We credit Representative Stark with leadership in devising legislation which has accelerated trends of integration and consolidation in the health care delivery system. Congress enacted what has come to be known as "Stark I" as part of the Omnibus Budget Reconciliation of 1989. The prohibitions of the statute were extended to a list of "designated health services" as part of the Omnibus Budget Reconciliation Act of 1993. During the initial work on the statute, we could not have anticipated the problems which we are now aware of.

We believe that changes to the statute would go far to encourage the cost-effective trends currently at work in the marketplace. Amendments are needed to repair some of the damage that has been created for a variety of transformational delivery system models by provisions in the law.

Final rules implementing the ban on referrals for clinical laboratory services are expected to be published shortly. HCFA has indicated that the final rules for Stark I will set the tone and provide guidance for implementation of Stark II. Stark II has extremely broad implications for physicians and any health care organization with which they do business.

The law prohibits a physician who has a financial relationship with an entity from referring Medicare and Medicaid patients to that entity to receive a designated health service. A financial relationship can exist as an ownership or investment interest in or a compensation arrangement with an entity. The law is triggered by the mere fact that a financial relationship exists; it does not matter what the physician intends when he or she makes a referral or whether he or she knows if a financial relationship exists.

In working with Congress and the Administration, AGPA has identified many areas of uncertainty and ambiguity in the statute since Congress passed Stark II in 1993. Without

further clarifying legislation, however, HCFA cannot resolve all of the problems apparent in Stark II. Consequently we recommend postponement of the effective date of the statute while Congress considers clarifying amendments.

Pending the publication of final regulations on DHS, which cannot reasonably be expected until 1996 or 1997, HCFA has indicated that enforcement will rely on "the language of the statute." In addition, HCFA has announced that it will begin compliance audits for these provisions once the final rule on clinical laboratory services is published.

Federal penalties which may result from a misinterpretation of the statute are potentially devastating. On March 31, 1995 the Office of the Inspector General (OIG) published final rules implementing civil money penalties, assessments, and an exclusion against any person who presents, or causes to be presented, a bill or claim the person knows or should know is for a service unlawfully referred under the self-referral statute, and has not refunded (within 60 days) amounts inappropriately collected for a prohibited referral. The OIG has announced its intentions to bring enforcement actions before HCFA has promulgated both sets of implementing regulations for Stark I and Stark II.

Absent clarification of a number of ambiguities related to the enumerated exceptions to the statute, we believe enforcement actions are unrealistic and improper.

Exceptions to Stark II

Several exceptions to the referral and billing prohibitions are set forth in the Stark law. Qualification for one of the enumerated exceptions is required if Medicare and Medicaid referrals for designated health services by a physician who has a financial relationship with an entity, including a group practice, are to be permitted. Some exceptions relate to both ownership/investment interests and compensation arrangements, and some relate to only one of these.

Specifically, the statute allows exceptions for 1) "physicians services provided personally by or under the supervision of a physician in the same group practice; 2) "in-office ancillary services;" and 3) "prepaid plans." We call your attention to the application of the exceptions because the standards for each exception must be met or the referral for a designated health service is viewed as a prohibited activity subject to all of the attendant penalties.

In the following sections we will demonstrate the breadth of unresolved issues which significantly interfere with the financial and clinical integration of a health care system. In the fullest sense of some reasonable interpretations of the statute, any organization providing designated health services in which the exception has been applied erroneously is subject to exclusion.

There are a number of exceptions related to both ownership and compensation arrangements: physicians' services when a physician refers to a member of the same group practice; certain in-office ancillary services furnished by solo practitioners and group practices; or and services furnished by certain organizations with prepaid plans (e.g., some federally qualified HMOs).

There are exceptions related only to ownership/investment interests: Ownership in certain publicly traded securities and mutual funds; DHS provided by a hospital in Puerto Rico; DHS furnished by a rural provider; or DHS provided by a hospital outside of Puerto Rico if the referring physician can perform services at the hospital and the ownership or investment interest is in the whole hospital (not in a subdivision of the hospital).

And there are exceptions related to compensation arrangements: payments made for the rental of office space or equipment; payments made to a physician (or immediate family member) who has a bona fide employment relationship with an entity; payments made to a physician or family member for personal services; payments involved in an isolated financial transaction; payments made by a hospital to a physician if the payment do not relate to DHS; payments made by a hospital to recruit a physician; certain payments resulting from a group practice's arrangements with a hospital when DHS are provided

by the group; or payments by a physician to an entity for items and services.

In-Office Ancillary Services Exception: One of the most common exceptions accessed by physicians in group practices to permit billing by the group practice entity to the Medicare program is the in-office ancillary services exception. This exception protects some (but not all) designated health services offered by group practices that meet specific standards. With the passage of Stark II, this exception is critical to enabling group practices to offer a full spectrum of coordinated medical services to their patients.

As presently constructed, the definition of the term "**group practice**" requires each member of the group to furnish substantially the full range of services the physician routinely provides within the group practice. A "group practice" is defined in the statute to be: 2 or more MDs, providing services in the name of the group, billing in the name of the group, and distributing the proceeds in a predetermined manner, and allocating overhead expenses. New provisions enacted as part of OBRA '93 require that no physician who is a member of a group may receive **directly or indirectly** compensation that is based upon the volume or value of his referrals; and, in order to qualify as a group, 75 percent of the physician-patient encounters of members of the group must be within the group practice.

Many of the definitional requirements of the Stark law are designed to limit the in-office ancillary exception to bona fide, integrated group practices. The Stark II definition of a group practice specifies that a physician in a group practice may be paid a share of overall practice revenue of the group or a productivity bonus based upon services personally furnished by the physician, or furnished "incident to" such physician's services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by the physician.

Contradictions in the Law

The OBRA '93 physician ownership and self-referral provisions have accelerated a trend in group practice financial relationships and in systems of compensation which eliminate incentives for overutilization of services. **But the Stark legislation is complicated and in some instances contradictory, consequently, the task of interpreting conflicting provisions in the statute perplexes many group practice leaders, and other providers, and appears to be equally baffling to HCFA.** Such confusion, when combined with the threat of enforcement and statutory stiff penalties, clearly chills the interest of group practices in offering DSH, even when doing so is beneficial to patients.

Several questions arise with respect to permissible compensation mechanisms. Clearly, physician members of a group can be compensated on a salaried, hourly, or fee-for-service basis for professional services personally furnished to patients or administrative services that benefit the functioning of the group, such as quality assurance or utilization review activities. It is unclear, however, the extent to which physician members of a group can receive compensation based on a percentage of revenue generated from ancillary services. It is extremely confusing that Congress expressly permits a bonus based upon "incident to" ancillary services, but also restricts the group practice from offering a bonus which varies directly based on referrals for those services.

Although distributions based on services ordered are prohibited after January 1, 1995, ancillary service revenue can be distributed to group practice members as long as the methodology for distribution does not include volume considerations. The distribution of ancillary revenue based upon ownership interests in a group practice or on an equal basis to all members of a group practice would be clearly permitted. An equal distribution of all ancillary service revenue to group members is not, however, required. To illustrate, departments within a large group practice, or individual physicians, may receive different proportions of ancillary service revenue if the distribution methodology was not volume driven. In this regard, historical data, such as patient satisfaction, outcomes, or years of service to the group practice entity could be considered. Utilization of historical data relating to personally performed services should also be permissible (e.g., the ratio of the revenue generated from the physician's personally performed services to total group practice revenue could be applied to all profit distributions, including ancillary service revenue). Utilization of historical data that is volume based (i.e., based upon past

percentages of referrals for ancillary services) would produce a compensation mechanism that would likely fail to comply with the Stark law requirements.

Integrated Delivery Systems: The physician ownership and self-referral legislation contemplates an environment in which physicians have few, if any, formal affiliations with other physicians or institutional providers. That environment is not one in which large multispecialty group practices find themselves. Rather, many group practices provide the physician component of a complex, integrated health care delivery system that has evolved over many years to serve the health care needs of large population groups. These systems have been created in response to customer-focused changes in the health care environment and specific expectations of patients. They provide the training ground for the physicians of tomorrow and the laboratory for the future's medical and scientific advances.

No exception to Stark exists for integrated health care delivery systems. Yet, referrals between and among the components of integrated systems are in the best interest of patients and intrinsic to the efficiency of such systems. The development of common services and facilities to avoid duplication and to conserve scarce resources is the cornerstone of an integrated health care delivery system, but the creation and use of these facilities might be curtailed by the Stark legislation.

Compensation Arrangements

For group practices and integrated systems of care, the physician ownership and self-referral statute breaks down primarily in the area of compensation arrangements. The following examples depict legitimate business circumstances that may be impaired by the self-referral compensation provisions. If Congress undertakes the task of clarifying the interpretation of the statute we would strongly suggest that the compensation arrangement provisions be revised. These provisions are redundant to the anti-kickback provisions which establish criminal penalties for payments to induce referrals.

Problems Arising From Self-Referral Compensation Provisions

Listed below is a sampling of the types of arrangements that may be impaired by the compensation prohibition on the self-referral law. This list is by no means comprehensive.

Shared Services

- In many instances, hospitals share services with large group practices, such as data processing, medical records, power plants, even clinical laboratories. These arrangements achieve cost efficiencies. Oftentimes one of the parties acts as the paying agent and is reimbursed by the other for its share of the expenses of the shared service based upon usage. Even where remuneration exchanged complies with the anti-kickback law, there is no apparent exception in the self-referral law that would apply to them.

Recruitment

- A hospital may recruit new physicians by paying a recruitment package for the relocation of a new physician to join a group practice that may be composed completely, or in part, of existing members of the hospital's medical staff. The payments to the group are designed as a "pass-through" directly to the recruited physician and are revenue neutral to the existing group. Assuming such payments otherwise would satisfy the self-referral recruitment exception if paid directly to a physician, technically the exception may not protect the recruitment payment to the group practice. Such arrangements are intended to increase the likelihood of the recruited physician's success in a new area, to simplify the accounting since the recruited physician generally is paid a salary as an employee of the group, and to take advantage of the ability to share overhead expenses and reduce costs.

- The self-referral recruitment exception is limited to recruitment of physicians from another geographic area. Thus, protection is not extended to recruitment of

physicians who are completing a local residency. (The proposed recruitment safe harbor under the anti-kickback law would extend such protection).

- The self-referral physician recruitment exception does not protect the recruitment of physicians who currently practice within the service area, but who will not be able to refer their existing patients to the hospital due to the nature of their previous practice (e.g., physician employees of HMOs, government clinics).

- The self-referral physician recruitment exception applies only to hospitals; group practice and other entities' recruitment efforts are not addressed by any exception and therefore are not specifically protected.

Leases

- The self-referral rental of space exception technically may not apply to the rental of non-office space, such as parking facilities, or to ground leases. Yet, group practices frequently lease such premises from hospitals and there is safe harbor protection available for such leases under the anti-kickback law. Also, it is not unusual for group practices to build their facilities on land leased from a hospital under a long-term ground lease.

- The self-referral lease exceptions may not protect commercially-reasonable short-term leases with physicians. Yet, such leases are desirable to permit physicians to assess a market before committing to a long-term lease or may be necessary in connection with a temporary relocation pending availability or completion of renovation of permanent space.

Practice Acquisition

- Hospital acquisitions of physician group practices may be stymied by the self-referral law because hospitals may not be able to pay cash for such practices and, instead, may issue notes to the physicians who remain in the practices. These notes may not be protected under the isolated transaction exception of the self-referral law, even if their terms are at fair market value.

Loans

- It is unclear whether secured or unsecured loans are considered ownership interests or compensation arrangements under the self-referral law. A loan may be desirable from a hospital to a physician group, for instance, as part of the initial capitalization of a physician/hospital organization (PHO) owned in part by physicians. If a loan is considered an ownership arrangement (because the statute defines ownership as through "equity, debt, or other means"), it is unclear whether the exception for ownership in a hospital as a whole would be available when the loan is from a hospital to a physician. Further, if a loan is considered a compensation arrangement (whether secured or unsecured) and is repaid at fair market value, the law still may not provide protection.

Management Service Organizations (MSOs)

- Group practice physicians are more frequently contracting for space, equipment, management, and other services with MSOs (that are at least partially owned by a hospital to which they make referrals and partially owned by the physicians). Existing self-referral exceptions may not permit physician ownership interests in such an MSO entity in some circumstances. Further, it is unclear whether payments from the group practice to the MSO for all the items and services provided may be based on a percentage of group practice collections.

Physician/Hospital Organizations (PHOs)

- The self-referral law may not protect the initial capitalization of a PHO (or an Independent Practitioner Association (IPA)) by a hospital. Yet, without such capitalization, the PHO (or IPA), which is a building block to managed care

arrangements, may not be established at all.

- A hospital may establish a PHO as a division of the hospital. Consequently, participating physicians' contracts with the PHO technically are contracts with the hospital itself. The contracts between the hospital and participating physicians may provide that physicians will perform services as required by the PHO's contracts with payors, at the negotiated rates under the payor agreements. The self-referral law may not protect third-party payor payments to the physicians that flow through the PHO so that the PHO can retain a portion of the payments to fund its operations and to facilitate participation in capitated arrangements.

Services Provided to Hospital Inpatients

- Physician-owned entities, other than group practices, frequently provide services under arrangements to hospital inpatients, such as dialysis. Even though dialysis is not a designated health service, it becomes one when provided to hospital inpatients. The self-referral law only protects such arrangements when provided by a group practice in accordance with an agreement in place as of December, 1989. However, such arrangements, whether established before or after 1989 and provided through physician-owned entities which are not group practices, may offer cost-efficiencies and otherwise satisfy the anti-kickback law.

Profit-Sharing with Physicians

- Hospitals may wish to pay employed physicians an annual bonus based upon the hospital's overall actual performance as compared to its budgeted performance. The self-referral law does not appear to protect this arrangement even though (i) profit-sharing is a common employee compensation mechanism; (ii) an employed physician's ability to affect overall hospital profits is insignificant; and (iii) the physician would be permitted to have an ownership interest in the hospital as a whole.

Medical Education Arrangements

- The self-referral law may not protect arrangements for medical education programs between hospitals and group practices or between a hospital and a university or its medical school. For instance, a hospital may provide new technology to a medical group as part of its teaching program for which no exception apparently exists.

Early Termination Clauses

- Many lease, employment, and personal services arrangements provide for the ability to terminate an agreement before the term expires, often after an initial year-long term has transpired. For instance, an agreement may exist between a hospital and a physician to provide services which are only required for a limited period of time, such as consultation services required in connection with the start up of a new hospital service. There would appear to be no logic to prohibiting a hospital from billing for services ordered by a physician simply because the hospital only required his or her consultation services for a period of less than one year.

AGPA Recommendations:

For group practices and integrated systems of care the physician ownership and self-referral statute breaks down primarily in the area of compensation arrangements. We believe that it was Congress' intent to promote systems of care which improve access to care, continuously improve the quality of services, and reduce costs. These simultaneous objectives are best achieved through the clinical and financial integration of services. The marketplace is demanding consolidated and integrated delivery system approaches in the transformation from fee-for-service to capitation and managed care.

To further promote these objectives, Congress must take the following steps to eliminate the ambiguity and uncertainty regarding interpretation of the physician ownership and self-referral statute. Barriers to integration, such as the compensation provisions of the statute, must be removed to allow such systems to align incentives and rewards with the objective of insuring the health of enrolled populations.

* Without clarification, HCFA faces a great deal of uncertainty about the intent of the law and the meaning of significant terms, conditions and exceptions in the statute. **In the absence of further guidance from Congress, we recommend postponement of the effective date of the statute for two years, or until final implementing regulations are published.**

* The continued evolution of health care options, which meet the needs of patients and payors, is cause to rethink the policies underlying physician self-referral restrictions. At a minimum, statutory and regulatory initiatives should preserve the intent of the in-office ancillary service exception and the ability of group practices to engage in the delivery of health care services as part of integrated systems of care, to continue innovation promoting cost efficiencies in the competitive market in which health care services are provided.

* Congress should clarify interpretations of the statute by eliminating the compensation arrangement provisions. These are redundant to the anti-kickback provisions which establish criminal penalties for payments to induce referrals.

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 overutilization of services. However, while the anti-kickback law is framed in terms of the intention to seek referrals, the self-referral law sets forth a "bright line" test and prohibits certain arrangements regardless of whether any intention to seek referrals exists or any overutilization results. Moreover, due to ambiguities inherent in the compensation provisions the self-referral law has the potential to be even more overreaching. 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.

Thank you for this opportunity to submit written comments. We stand ready with the resources of the Association to support your efforts to improve the nation's health care system.

Chairman THOMAS. Thank you, Dr. Balfour.
Mr. Griffin.

STATEMENT OF PHIL GRIFFIN, VICE PRESIDENT, PUBLIC POLICY, PREFFERED ONE, MINNESOTA, ON BEHALF OF THE AMERICAN MANAGED CARE AND REVIEW ASSOCIATION

Mr. GRIFFIN. Thank you, Mr. Chairman. Good morning.

Chairman THOMAS. I believe your mike is not on. Down on the base there should be a switch.

Mr. GRIFFIN. Mr. Chairman, this one seems to be working. Good morning, Mr. Chairman, Members of the Subcommittee, my name is Phil Griffin. I am vice president of public policy at Preferred One, a Minnesota-based preferred provider organization, with over 450,000 enrollees.

I am testifying today on behalf of AMCRA, the American Managed Care and Review Association as chairman of their public policy committee. AMCRA is the national trade association representing the full spectrum of MCOs, managed care organizations, such as HMOs, health maintenance organizations, and PPOs, preferred provider organizations. AMCRA's 500-plus member companies provide health care services to over 85 million Americans.

In addition, AMCRA's board of directors is currently composed of 50 percent managed care physicians and 50 percent managed care chief executive officers. Thus, AMCRA can provide the Subcommittee with a unique perspective on the self-referral law.

The physician self-referral law was enacted to address overutilization in the Medicare and Medicaid fee-for-service programs. Unfortunately, the broad reach of the self-referral ban has had many unintended consequences for MCOs. Moreover, the law is affecting managed care arrangements far beyond Medicare and Medicaid. Significantly, many managed care organizations may be unaware of the legal constraints imposed by the physician self-referral law because they do not view themselves as either designated health service providers or as servicing a Medicare or Medicaid population. Yet, even MCOs with only commercial business will discover on closer examination that their employer group health plan customers include Medicare eligibles, such as working aged and retirees.

Under the self-referral ban, MCOs with any degree of physician ownership generally cannot furnish designated health services. Yet increasingly, managed care organizations are finding that it can be most effective to furnish certain designated health services and are seeking to incorporate these services directly into their business operations. For example, in my home State of Minnesota, we have seen a movement toward vertical integration in the three major health plan companies. This movement has been spurred by the employer community and its demands for cost-effective quality health care services.

At the same time, managed care organizations are seeking ways to make the provider community a partner in the delivery of cost-effective quality health care. One way of doing this is to offer physicians equity participation in the organizations. Similarly, many provider organizations are adding an insurance component in order to be in a position to accept financial risk for health care services

consistent with State insurance regulation. Overall, the line between payer and provider is becoming blurred with significant consequences under the physician self-referral law.

The self-referral ban also constrains vertical integration of MCOs when physicians have only contractual arrangements with the organizations. Any provider agreement with a managed care organization could be considered a compensation arrangement if not otherwise exempt. Once a physician has a compensation arrangement with an entity, the law precludes the physician from referring to that entity for designated health services unless the provider agreement meets certain criteria, including compliance with HCFA's forthcoming physician incentive plan rule.

This regulatory scheme mixes apples and oranges. The incentive rule is intended to address potential underutilization in Medicare and Medicaid managed care arrangements, whereas the purpose of the physician self-referral law is to prevent overutilization in the Medicare and Medicaid fee-for-service programs. In its rule, HCFA has proposed a complicated mathematical scheme for regulating the financial risk that physicians may accept from referrals. Once the rule is final, a physician only will be able to refer Medicare managed care patients to the HMO's or PPO's in-house laboratory or radiology facility if the physician's compensation arrangement with the MCO meets the guidelines of the rule. As a result, this rule, designed to regulate Medicare managed care, will now regulate all commercial managed care arrangements, which may involve Medicare eligibles only incidentally.

AMCRA does appreciate Congress' past efforts to provide exceptions for managed care activities from the broad reach of the self-referral law, but the managed care exceptions adopted thus far are not sufficient. The current prepaid exception extends only to enrollees of Medicare contracting and federally qualified health plans and to certain other statutorily recognized cubbyholes for managed care organization dealings with the Medicare Program. Medicaid managed care does not qualify for any exception, nor does the current statute protect State-licensed HMO, PPOs or even Medicare contracting or federally-qualified HMOs to the extent they also offer PPO, point-of-service or non-federally-qualified products. Yet it is the PPO and point-of-service managed care products that are especially consumer friendly, allowing patients full access to non-network providers through the payment of higher out-of-pocket costs rather than requiring patients to use plan providers.

By protecting only formal Medicare managed care and other governmental programs, the self-referral law operates to actually grant more latitude to managed care organizations with substantial Medicare operations and little latitude to MCOs with predominantly commercial business. For instance, the law would presently allow a Medicare contracting health plan to contract with a physician-owned laboratory service to service the Medicare risk or contract enrollees. However, a health plan that only incidentally serves Medicare beneficiaries would be prohibited from doing so.

It is time to adopt a reasonable managed care physician self-referral policy that acknowledges the role of the marketplace in controlling overutilization in managed care while maintaining quality of care. The success of managed care organizations depend upon

the ability to market to employers and their employees quality, affordable, and comprehensive care.

Managed care organizations control costs not only through negotiations for lower prices, but also through the adoption of utilization review policies and by placing providers at financial risk for health services they furnish and order. Each managed care organization adopts the combination of utilization review, financial risk and quality assurance measures it believes best to control utilization and provide quality.

If an MCO is unsuccessful in controlling health care costs or delivering quality health services, it will suffer from a market standpoint. The market will not tolerate managed care arrangements that lead to overutilization, lower quality health care, and increased costs for employers and consumers.

AMCRA recognizes the legitimate role of the Federal Government to regulate in order to eliminate known abuses in the Medicare and Medicaid managed care programs. Yet, we do not understand why MCOs serving largely commercial populations are subject to this complex Federal regulatory framework and to the high costs associated with regulatory compliance, when we are aware of no data demonstrating that physician investment in managed care organizations leads to the abuses typically associated with the physician self-referral law.

Managed care is part of the solution, not part of the problem. Managed care's goal of controlling overutilization is entirely consistent with the governmental objectives in limiting physician self-referral. Nevertheless, a more balanced regulatory approach toward managed care organizations with respect to physician self-referral is plainly appropriate.

Mr. Chairman, we stand ready at AMCRA to assist you and Members of the Subcommittee as you pursue this investigation. If we can provide any answers to questions or help in any way, please feel free to call on us. Thank you.

[The prepared statement follows:]

TESTIMONY OF E. PHIL GRIFFIN
AMERICAN MANAGED CARE AND REVIEW ASSOCIATION

Good morning Mr. Chairman and members of the subcommittee. My name is Phil Griffin. I am Vice President of Public Policy at Preferred One, a Minnesota-based Preferred Provider Organization with over 450,000 enrollees. I am testifying today as Chairman of the Public Policy Committee of the American Managed Care and Review Association (AMCRA). On behalf of AMCRA, thank you, Mr. Chairman, for the opportunity to provide testimony on the managed care implications of the federal "physician self-referral law"[1] before the Subcommittee on Health of the Committee on Ways and Means.

AMCRA is the national trade association representing the full spectrum of Managed Care Organizations (MCOs), including Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), Independent Practice/Physician Organizations (IPAs), Utilizations Review Organizations (UROs) and Physician-Hospital Organizations (PHOs). AMCRA member companies provide approximately 85 million Americans with a health care choice that emphasizes the appropriate use of health care facilities and services, resulting in high quality health care at an affordable cost. With over 500 member organizations, AMCRA also includes a broad-based membership of allied health professionals who provide services to MCOs. In addition, the Board of Directors of AMCRA is currently composed of 50% managed care physicians and 50% managed care organization CEOs. Thus, AMCRA is uniquely positioned to provide the subcommittee with a combination provider/managed care organization perspective on the physician self-referral law, as well as on other health care issues.

The federal physician self-referral law was enacted to address the abuses thought to be associated with physician self-referral in a fee-for-service health care system. In other words, the law was adopted to address the potential for overutilization in the Medicare and Medicaid fee-for-service programs when a physician has an opportunity to profit financially from his or her referrals.

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[1] § 1877 of the Social Security Act

Specifically, the physician self-referral law prohibits a physician from making a referral to an entity for the furnishing of certain "designated health services," if the physician has a "financial relationship" with that entity, unless the financial relationship falls squarely within one of the statute's enumerated exceptions. A financial relationship includes "ownership or investment interests" as well as "compensation relationships."

Unfortunately, the broad reach of this self-referral ban language has had many unintended consequences for the health care industry generally and for MCOs in particular. Moreover, the self-referral ban is affecting managed care arrangements and transactions far beyond the Medicare and Medicaid programs. Significantly, many managed care organizations may be unaware of the legal constraints imposed by the physician self-referral law because they do not view themselves as either designated health service providers or as servicing a Medicare or Medicaid population. Yet even MCOs with only commercial business will discover, on closer examination, that their employer group health plan customers include Medicare eligibles such as working aged and retirees. The Medicare Secondary Payor law requires these Medicare eligibles to be given the same benefits as other employees.

Under the physician self-referral ban, MCOs with any degree of physician ownership generally cannot furnish designated health services directly -- in other words, own and operate, for example, a laboratory, radiology facility or hospital as a line of business or subsidiary. Yet, managed care organizations are increasingly finding that it can be more cost-effective to furnish certain designated health services directly, and are seeking to "vertically integrate" as to those services -- that is, incorporate these services directly into their business operations, much as staff model HMOs always have operated. This trend toward vertical integration can be expected to continue as the managed care marketplace becomes more competitive. For example, in my home state of Minnesota, we have seen a movement toward vertical integration in the three major health plan companies. This movement has been spurred by the employer community and its demands for cost-effective, quality health care services.

At the same time, managed care organizations are seeking ways to make the provider community a "partner" in the delivery of cost-effective, quality health care. One effective means of doing so is to offer physicians equity participation in the MCO. Similarly, many provider organizations are adding an insurance component in order to be in a position to accept financial risk for health care services consistent with state insurance regulation. Overall, the line between payor and provider is becoming blurred, with significant consequences under the physician self-referral ban.

The physician self-referral law also may be implicated if a managed care organization, which is already vertically integrated with respect to designated health services, seeks to acquire an MCO with any degree of physician ownership.

If the physician-owned organization and/or its owners take back a note from the purchaser, or accept stock in the acquiring managed care organization for all or a portion of the purchase price, the physician-owners may be deemed to have a continuing ownership interest in the acquiring managed care organization under the physician self-referral law. So long as the note is outstanding, or the physicians hold the stock, the physicians cannot send Medicare or Medicaid patients to the acquiring managed care organization for any vertically integrated designated health services.

The physician self-referral law also constrains vertical integration of MCOs when physicians have only contractual arrangements with the organizations. Any provider agreement with a managed care organization could be considered a "compensation arrangement," if it is not otherwise exempt. Once a physician has a compensation arrangement with an entity, current law precludes the physician from referring to that entity for designated health services unless the provider agreement meets certain criteria, including compliance with the Health Care Financing Administration's (HCFA's) forthcoming "physician incentive plan rule."

This regulatory scheme mixes "apples and oranges." In contrast to the self-referral ban, which is designed to prevent overutilization of health care services, the physician incentive plan rule is intended to address potential underutilization in Medicare and Medicaid managed care arrangements by regulating the amount of financial risk that physicians may accept for referrals.

In its rule, HCFA has proposed a complicated mathematical scheme for regulating financial risk for referrals.[2] Once the rule is published in final form, a physician will only be able to refer managed care organization patients to the organization's in-house laboratory or radiology facility if the physician's compensation arrangement with the MCO meets the guidelines of the rule. As a result, this rule, designed to regulate Medicare managed care, will now regulate all commercial managed care arrangements which may involve Medicare eligibles only incidentally.

AMCRA does acknowledge and appreciate Congress's past efforts to provide exceptions for some managed care activities from the broad reach of the physician self-referral ban. But the managed care exceptions adopted thus far are not sufficient to protect the broad spectrum of managed care activities. The current "pre-paid plan" exception extends only to enrollees of Medicare contracting and federally qualified health plans and certain other statutorily recognized "cubbyholes" for managed care dealings with the Medicare program.

Medicaid managed care does not qualify for any exception. Nor does the current statute protect state licensed Health Maintenance Organizations (HMOs) or Preferred Provider Organizations (PPOs), or even Medicare contracting or federally qualified HMOs to the extent that they also offer PPO, point-of-service or non-federally qualified products. Yet it is the PPO and point-of-service managed care products that are especially consumer-friendly, allowing patients full access to non-network providers through the payment of higher out-of pocket costs, rather than requiring patients to use the plan's provider network.

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[2] 57 Fed. Reg. 59024 (December 14, 1992) to be codified at 42 CFR pt. 1003.

Each managed care organization adopts the combination of utilization review, financial risk and quality assurance measures it believes is best to control utilization of services and to provide quality health care. If an MCO is unsuccessful in controlling health care costs or delivering quality health care services, it will suffer from a market standpoint. If it is a PPO that sells its provider network and utilization and quality control program to self-insured employers and other third party payers, it will lose contracts. If it is an HMO or insurance company, it will lose subscribers (that is, market share). The market will not tolerate managed care arrangements that lead to overutilization, lower quality health care, and increased costs for consumers and employers.

AMCRA acknowledges the legitimate role of the federal government to regulate in order to eliminate known abuses in the Medicare and Medicaid managed care programs. Yet, AMCRA is aware of no data demonstrating that physician investment in managed care organizations leads to the abuses the physician self-referral law was designed to eliminate. We do not understand why MCOs serving a largely commercial population are subject to this complex federal regulatory framework, and to the costs associated with regulatory compliance, in an area where there is no documented evidence of abuse.

Managed care is a part of the solution to the current crisis in health care, not part of the problem. Managed care's overriding goal of controlling overutilization of health care services is entirely consistent with governmental objectives in limiting physician self-referral. Indeed, the managed care community and the federal government are on the same side with respect to provider fraud generally. Many of AMCRA's members are active in the joint private/public initiatives to eliminate provider fraud in all third party payment programs. Nevertheless, a more balanced regulatory approach with respect to physician self-referral is plainly appropriate. Unnecessary regulatory constraints on managed care activities, and the costs associated with regulatory compliance, only contribute to the rising cost of health care, and impede health plans from adopting strategies that encourage the provision of cost-effective, quality health care services.

By protecting only formal Medicare managed care and other governmental programs, current law operates to actually grant more latitude in the physician self-referral area to managed care organizations with substantial Medicare operations, and little latitude to MCOs with predominantly commercial business. For instance, the physician self-referral law presently would allow a Medicare contracting health plan to contract with a physician-owned clinical laboratory to service Medicare risk or cost contract enrollees. However, a health plan that only incidentally serves Medicare beneficiaries as part of an employer group health plan, and merely coordinates benefits with the Medicare program, would be prohibited from doing so. Thus, a law intended to regulate Medicare and Medicaid physician self-referral is actually more restrictive with respect to health plans with substantially commercial business, and less restrictive as to Medicare operations.

It is time to adopt a reasonable managed care physician self-referral policy that acknowledges the role of the marketplace in controlling overutilization in managed care, while maintaining quality of care. The success of a managed care organization depends on its ability to market to employers and their employees affordable, quality health care coverage--that is, comprehensive, quality health care coverage at lower premium cost. Like the federal government, managed care organizations know that health care costs are a function of both price per service and volume. Thus, managed care organizations control costs not only through negotiations for lower prices (i.e., discounts), but also through the adoption of utilization review policies and by placing providers at financial risk for the health care services they furnish and order. Financial risk includes not only capitation--a fixed fee per enrollee irrespective of the actual volume of health care services delivered--but it also includes withholds and bonuses that reward cost-effective behavior.

Mr. Chairman, thank you once again for the opportunity to testify before this subcommittee. AMCRA stands ready and willing to assist this subcommittee as it examines changes to the physician self-referral law, as well as with any other issues related to the Medicare and Medicaid programs. I will be happy to answer any questions you, or any other members of this subcommittee, may have at this time.

Chairman THOMAS. Thank you very much, Mr. Griffin. Thank the whole panel.

Does Mr. McCrery wish to inquire?

Mr. MCCRERY. Thank you, Mr. Chairman. Just one question to Mr. Warden.

Mr. Warden, can you give us an idea of what the reporting requirements in the law would mean to your health system?

Mr. WARDEN. The reporting requirements, what they would mean to our system? Well, I think that they would mean that we would have to document the different kinds of transactions that we have. We would have to be able to document the referral arrangements that we have within our system. We would have to document the way in which central services are provided, and what the relationship of that is to the physicians in our group.

We would also have to be able to document the organizational arrangements between fee-for-service physicians and our hospitals and the different kinds of organizations that get created as a result of the partnerships, such as PPOs and MSOs, and the many different arrangements that occur.

Mr. MCCRERY. You do not presently have such a reporting regimen in effect? In other words, are you going to have to create this reporting regimen?

Mr. WARDEN. We would not have to create a reporting regimen because I think most of us recognize that these kind of relationships have to be documented. Quite the contrary, I think the problem that occurs is that in trying to create these relationships, quite often the need for such a wide variety of arrangements become a deterrent because the attorneys representing the physicians who are going to be part of these arrangements are very leery about what the impact may be on the individual physicians who contract with us.

Mr. MCCRERY. Thank you, Mr. Chairman.

Chairman THOMAS. Does Mr. Stark wish to inquire?

Mr. STARK. Yes, just a couple of comments, Mr. Chairman. I want to welcome Dr. Bristow from California, but I am a little bit confused and maybe subsequent to the hearing the AMA could correct me, but in 1991 and 1992 the AMA policy, and I am quoting relative to self-referral, is "presumptively inconsistent with the physician's fiduciary duty to their patients," and in your testimony today you indicate investing and referring as a direct extension is ethical and desirable.

My staff finds that somewhat inconsistent. Maybe it is semantic difference, but I would be interested to know the definitive statement of the AMA. Let me suggest that the panel today may be beating a dead horse, that they may be among themselves their own problem. I do not remember who represents which groups, but for the most part group practices that charge a set fee to the patient or to the insurance company and provide generally all services are exempted. But when we exempt them, we did not exempt the hospitals, so the hospitals are losing business to the group practices, and they are saying to us, let the hospitals get that exemption too, because the group practices are now not coming to the hospitals and paying us to do x rays and tests, and there are other changes.

On the one extreme if you have just the normal fee-for-service indemnity insurance community—which I suppose people would say is disappearing, but I do not think it is really all over the country—and if a radiologist calls up a GP or an internist and says I will give you $100 cash for every patient you send me, I doubt if any of you would say that is not unethical and ought not to be tolerated.

Is that an example of where we would be on that end of the scale? Anybody think that is fair? You all agree, I assume, that it is off the table. On the other hand, I would agree, and I think you all would agree, that in a capitated system where a patient pays $1,000 or $2,000 a year and all services are provided, there is hardly any attempt, any real need for worrying about this arrangement. But there is a new phenomena arising, and that is underutilization.

What if in that capitated plan you are paying Dr. X a bonus not to refer to a psychiatrist or not to put a person in the hospital? I think you all would say that is wrong, particularly if you give the guy some kind of a commission for every case withheld—if you could figure out when they should go to the hospital and they withheld it. We are getting complaints about withholding services in managed care or denying services.

Now, so this may swing completely the other way. There isn't going to be much referring for fees anymore because everybody has got some kind of a deal to be in a group practice. It may be the other side of the coin. It may be that the problems may exist in denying services or products or referrals outside of the system. We are beginning to hear anecdotal evidence.

You all may have differences depending on how you bill for your services, receive your income, or provide the care. I am not sure that you are not a part of the problem. As soon as we set a standard for Dr. Deggy's old clinic, then it may not fit into what works for Kaiser or for one of Mr. Warden's members in the Hospital Association, and I am not sure that you want us to say there is only one standard of managed care.

Right now, there are an awful lot of definitions of managed care. We did not create those. In other words, there are probably 500 different corporate structures and partnership structures and contractual structures in managed care. I do not know how we could possibly write a law to fit all of those. What I am saying is that this is not that easy on either side of this podium to do what I think we could all agree is reasonable.

Now, the Chair has a problem, HCFA has a problem, and Members will have a problem. We won't be able to solve it if you all as a group cannot get some standards. I know that is harder to work for because that is confining your ability to be creative, but that may be the price of a more efficient medical delivery system that we cannot, each one of us, be real creative in how we bill, how we collect, how we practice. I thank the witnesses for sharing with us their problems, but I also want to come back to them and say try and work out some of these differences among yourselves, then our legislation obviously will not impact each of you differently. Thank the Chair for indulging me in those comments.

Chairman THOMAS. Mrs. Johnson.

Mrs. JOHNSON of Connecticut. Thank you, Mr. Chairman. Mr. Wenzel, your comments about a streamlined law really do interest me. We passed this law 6 years ago. We still do not have permanent, final regulations because it is terribly complex, and it is also going to be impossible, frankly, to write regulations that are going to be good for patients and good for providers.

I have been anguished to see how some of my elderly constituents have been desperately inconvenienced by this law and costs actually expanded rather than contracted by Washington trying to define what is going to be an ethical cost-effective system.

Now, I notice Mr. Stark's comment about capitated versus fee for service, and I agree with him on that. I would like to have the panel's general comment across the board on Mr. Warden's suggestion that we adopt an exception for all those situations in which there is risk sharing, not just capitation, but incentive pooling, per diem payment arrangements, withholds, could you amongst yourselves over the course of the next few days or weeks come to some clearer conclusion about what kinds of integrated systems actually manage payments in such a way that the concerns that led to the self-referral law are no longer operative? There is, it seems to me, a whole spectrum now of compensation arrangements that ought to exclude a group from the coverage of this law because the motivation and the possibility and the opportunity is simply no longer there. That kind of help would be very useful at this time.

I think we need from you clear examples of how you think a simplified or streamlined law would interact with current law, which is very tough. The current legislation that we had on the books before we passed the self-referral ban also was very tough. If you could show us which of the problems that led to the law 6 years ago would be addressed by streamlined law and which would not, that would be very helpful to us because one of the problems in this area is that we go home and we are faced with anecdotes, none of which completely addresses the problem or reveals the solution, so we really need your help in seeing how we streamline this law and what the implications of recent developments are for it.

Any comments you care to make, I would be happy to entertain, since I have the time.

Dr. Bristow.

Dr. BRISTOW. Yes, Congresswoman, I would like to respond a little bit to the comments that you made. Let me first say that you are absolutely right. The law was written based upon certain assumptions 6 years ago that increased utilization, implied misutilization. That was never proven. We would encourage that studies be done to see whether or not the care that was given was appropriate care.

I can think of several reasons that would warrant increased utilization by certain physicians. Those physicians who are treating patients who are chronically ill would very likely order more laboratory work. Those physicians who are treating patients that have more serious illness will very likely have more laboratory work. Those physicians who are better trained, more sophisticated and who are more in tune with preventive medicine approaches will very likely order more laboratory work.

The State of Florida is said to have a decidedly increased percentage of laboratory services being done. The State of Florida also has a disproportionate share of our elderly population. So, my word is that, first of all, I think we should check to find out whether or not the excessive use of services is truly inappropriate.

Second, in terms of a more streamlined approach, we in the profession are equally as concerned as the Congress to make sure that those individuals who are not using the system properly are identified and dealt with appropriately. We would suggest that you have HCFA use physician profiling to determine who are the outliers, then focus attention on those individuals to find out is it appropriate for you to be doing more, whatever it is, than other physicians in the same specialty.

There may be a rational explanation along the lines of what I just finished saying, and if that is the case, fine. If not, having identified where the problem is, take care of the problem. I would, with all due respect, suggest that in some ways this is sort of, this series of laws is sort of the Bubba Smith approach to oversight, and most of you know Bubba Smith was a very famous defensive player in professional football who was known for going into the opposing back field and gathering up all of the players and then sorting them out until he found the one who was carrying the ball.

Now, what this law tends to do is it imposes a great deal of limitations in a variety of ways, which you have heard this morning, in an attempt to find who is misutilizing the system, overutilizing and the fashion. We would suggest that there may be ways to do that which would not be quite as disruptive, and I will end my comment there.

Mrs. JOHNSON of Connecticut. Dr. Bristow, I do just want to mention, what you say is absolutely true, and if you look at the data that drove us 6 years ago, a lot of it just indicated that certain physicians referred more if they owned a facility. It did not look at whether they were in a specialty that required more tests, and maybe they had invested in the facility because there wasn't the quality of testing available otherwise, and so what you are really saying is that the old broad brush of volume no longer should play the role in our thinking because, after all, we passed it 6 years ago. Remember, we are talking about data that is now 10 years old.

When we pass legislation, it takes us 2 years to do it. It relies on data 2 years old, so the data at that time was primitive. What you are really saying is we need to look, using profiling, at whether the physician's performance is within norms or not, and then afterward look in greater depth at those areas in which they are not. That can even be done on a network-by-network basis now that we have more integrated networks, which is cheaper for the government and easier to investigate. But, developing that kind of approach for us as a group so we have a more integrated overview would be very helpful to us.

I see that my time has expired. If any of you want to communicate more about this, I think one of the most important things that we could do this session is to fix this so that we do address the underlying concerns of Mr. Stark's initial proposal of a number of years ago, and at the same time enable those concerns to not im-

pede the modernization of the health care delivery system. Thank you.

Chairman THOMAS. Doctor, was that quote attributable to Gene Big Daddy Lipscomb. The quote about gathering up the back field was Gene Big Daddy Lipscomb, wasn't it?

Dr. BRISTOW. I stand corrected.

Chairman THOMAS. I think it was. It used to be a method in the past. Apparently it is still alive.

Mr. Christensen, do you wish to inquire?

Mr. CHRISTENSEN. Mr. Warden, you have had a lot of success up at Henry Ford. Has the self-referral law been a barrier to your integration efforts or, if not, why?

Mr. WARDEN. I think the law has been a barrier to the extent that we are a group practice, but we also have 1,200 fee-for-service physicians in our system. We have hospitals that we own and hospitals that we contract with. We also own a large HMO with about 500,000 enrollees. The problems we encounter are the issues related to the need for exceptions for the different kinds of arrangements necessary to develop preferred provider organizations or physician hospital organizations.

For instance, in a lot of cases it is not clear whether you are breaking the referral law or some of the other statutes when you ask physicians to invest jointly with a hospital to create a physician-hospital organization so that they can then contract with a managed care entity. In many cases it is not just our own managed care entity, but several others on the outside, and there are issues related to that. There are issues related to the whole question of what services need to be located centrally and what can be distributed to other satellites which is something that Mr. Wenzel talked about. In many cases it is advantageous to the patient to be able to place those facilities in their community, keeping in mind that in a State like ours where we have a certificate of need law, you often do not have a proliferation of MRIs or other equipment that might cause over utilization concerns.

There also are concerns related to physicians who are paid a small fee to oversee a particular program, but who also refer their patients to that program, such as in kidney dialysis or oncology. This often occurs in community hospitals where the physicians are not part of the medical group practice arrangement. There are a lot of examples, and I think in most cases we are not sure whether we are breaking a law, but we are looking over our shoulder and trying to be very careful about how we do things.

Mr. CHRISTENSEN. Mr. Griffin, if you could just briefly give me some ideas on another issue that we are looking at and that is the Medicare situation, especially the gatekeeper situation in terms of managed care. I have talked to a lot of my friends in Omaha who are specialists that do not especially like the movement toward managed care.

How can we fix that situation? Maybe you could address that in a written answer because I know I am out of time. I do not know that managed care is the panacea in terms of the Medicare crisis.

Mr. GRIFFIN. Mr. Chairman, Congressman Christensen, just very briefly, managed care organizations do include gatekeeper organizations, but they include a variety of other types. Our PPO does

not have a gatekeeper concept so people can self-refer to specialists if they would like to.

There is a concern within managed care organizations with this issue. Some organizations are now offering a product that has been very popular, particularly in our marketplace in Minnesota, namely is a point-of-service plan which allows self-referral outside the panel. About 95 percent of the policies that are sold by the two largest HMOs now in Minnesota are point-of-service products which allow people to maintain that choice. It has become very popular in the marketplace, not because of regulation, but because of demand by employers for that service.

Mr. CHRISTENSEN. Thank you. Thank you, Mr. Chairman.

Chairman THOMAS. Mr. Ensign will inquire.

Mr. ENSIGN. Thank you, Mr. Chairman. Not really directed at any one person, I would like to make a couple of comments, then have your comments on it.

As a practicing veterinarian, I experienced a lot of the self-referral because we had to do a lot of this ourselves. I mean we had a lot of this stuff in-house, and we referred it to ourselves, but the client understood that it was our equipment, and they understood we were referring to ourselves.

Occasionally, there are specialists. I mean there are subspecialists and specialists in veterinary medicine now where you are referring out, and that is obvious, but they also know when you are referring in-house. I used to do endoscopy myself. When I would refer that they knew I was doing that, they knew I owned the endoscope. It would seem to me and being through some of the group practices out there, especially one cardiology practice that I recall last year that it was incredible, that we have this self-referral law in Nevada that you cannot refer, and the burden that it puts on patients having to go across town or whatever it is, it seems to put a tremendous burden on the patient as well.

It costs more money in the long run in a lot of these cases. I will agree that there are some abuses. I see it in veterinary medicine. I see some abuses, but I think that the abuses are small percentagewise, and it would seem to me that if we just introduced, I think Mr. Stark mentioned it earlier, something about sunshine laws, where if you are referring to someplace that you own, if you are required to at least let people know, it would seem to me that that would be a better answer instead of having all this regulation. You cannot do this, you cannot do that, just inform people and then it is up to them to make that choice. Anybody's comments?

Mr. WENZEL. I would agree 100 percent on that. It takes place in both rural and urban areas. Example, in a rural area, we have a location where we have a mammography unit that moves once a year in order to get the entire population actually screen. Now, of course, under the current regulations that is not permissible because we do not have any physicians practicing on that site. The same thing is true for physical therapy. A group of orthopods with their physical therapy across town located so that it can be of great convenience, particularly to the elderly patients who we are talking about here, again is not permissible. These are the kinds of things that inconvenience a great number of patients.

I like the idea of profilings. As a matter of fact, our research institute at MGMA is currently doing a major profiling project under Robert Wood Johnson. We are studying the very issues that Congresswoman Johnson mentioned, and these are the kinds of things that I think we really need to do not only to find abusers, but also to change the behavior of physicians, which is also important.

Dr. BRISTOW. Mr. Chairman, I would love to say just a few words about that. The AMA's Council on Ethical and Judicial Affairs has taken exactly the position that was just outlined by the Congressman. We have said that it is permissible for physicians to invest in facilities to which they would like to refer patients, but they have got to satisfy certain criteria.

Among these are, there must be full disclosure to the patient. There should be no special incentive to the physician to become an investor. Others other than physicians should be able to equally invest in this venture, and there should be some internal utilization and review. I like to sum it up when I talk to doctors around the country about what it is that the council expects of doctors.

I tell them that the way to approach investments that would impact their patients is as though they were going to go to church on Sunday morning and have their mother sitting at their side and then have the minister outline their business deal from the pulpit. If they cannot do that, then it is not for them to do if it relates to their patients. That is the attitude that we are trying to promote, that it has to have full disclosure, just as you said.

Mr. ENSIGN. Very good. Thank you, Mr. Chairman.

Chairman THOMAS. I want to thank the panel. Notwithstanding, that test which is a pretty difficult one, the Chair has some concern about potential philosophical ax grinding in this area for a couple of reasons. One, in examining the methodology that was really used, at the beginning I said that it is obviously a priori that somebody who has the ability to refer to themselves to make money and who is so inclined and only has to answer to themselves probably might engage in the act.

But all of the methodology that I saw underscoring and the connection between the physician and the ownership, nowhere did I see what I would consider an adequate study approach looking at the final result; that is notwithstanding the fact that there were more referrals, not withstanding the fact that the procedure costs more money than some other procedure, in the final analysis was the diagnosis made quicker, was the cost actually less?

They never completed the analysis. They simply made the link and from that they moved forward, so from a methodology point of view, it has bothered me a lot. The fact that it makes it easier on the government if you simply show the relationship exists instead of proving intent seems to me to tip it the wrong way. If we are after crooks we ought to be comforted with the fact that where there is intent you go get them. So, you have got a chilling effect.

Then, I guess if you are in control of a body which passes laws for 40 years between the fifties and the nineties, the absolutely wrong timeframe to move a law like this is in the nineties when for the first time in a generation you are getting a lot of innovative interaction which is going to save the society money, and then last

and maybe this is where we need a comment from you, I guess I would put up with all that if I honestly believed that you could stop the unethical self-referral with this law. I guess that is my bottom line.

Yes, you deal with transactional changes and structural arrangements, but does it really ultimately stop someone who is interested in doing this in the first place, which I guess is the reason we wanted to start down the road of stopping this practice of people who intentionally were doing this. Any comments from anyone?

Dr. BRISTOW. Congressman, I believe you can have legislation that will, if not stop, certainly seriously impair those who are abusing the system.

Chairman THOMAS. Is this the legislation that does that?

Dr. BRISTOW. My concern is that it is too broad brush, as I said before, and what we need to do is focus on where the problems lie, and I think there are tools that we can use to identify where the problems lie, and then the profession certainly would join you enthusiastically in trying to get at where those problems are and treat them.

Mr. WARDEN. I think it relates, Mr. Chairman, to the way that everyone—whether in the private market or through Medicare or Medicaid purchases health care. If you are a prudent buyer and if some very clear and strict guidelines are established for these kinds of things, I think that you can expect people to comply because if they do not, they cannot be contractors.

Mr. GRIFFIN. Mr. Chairman, just briefly, I think we have dealt with the fee-for-service system in Medicare and Medicaid that you are examining here for 30 years that has collected a great deal of data. It is only within the past few years that we have really begun to gather the data on effectiveness and in trying to work with physicians to develop the best guidelines and protocols for treatment and then to measure the impact of those.

We are not there completely yet in managed care. Fee-for-service is coming with us, but we think that is the answer to determining whether or not referrals are appropriate and not rather than some broad law which just says some are inappropriate because of this reason or that.

Chairman THOMAS. More data profiling and guidelines are the answer to a lot of other problems as well, and we have been remiss in not collecting data in a way that allows us to move forward on that. I am just always concerned about a law in which before the regulations are promulgated, there are books on the bookshelves, one which is entitled, "Navigating Your Way Through The Federal Physicians Self-Referral Law,"—seven coauthors, all lawyers. It does not bode well when the books explaining the laws are on the shelves before the regulations are not even cold, but not printed. I want to thank the panel.

Dr. Balfour, did you want to say something?

Dr. BALFOUR. Thank you, Mr. Chairman. I just want to say if we eliminate the compensation arrangements, then I think the risk-sharing exceptions would not be needed. I think that is the answer.

Chairman THOMAS. I want to thank you very much. Once again, our goal here is to try to get sufficient information to perfect the process. I want to thank you for your contribution.

Dr. BRISTOW. Thank you.

Chairman THOMAS. The next panel will consist of a panel of one, George Grob, who is the Deputy Inspector General from the Department of Health and Human Services. Mr. Grob, as with the other panelists, I would indicate that if you have a written statement it will be made a part of the record without objection, and you may proceed as you see fit to inform us.

STATEMENT OF GEORGE F. GROB, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH HUMAN SERVICES

Mr. GROB. Thank you, Mr. Chairman, and good morning and to the other Members of the Committee as well. My name is George Grob, and I am the Deputy Inspector General for Evaluation and Inspections in the Department of Health and Human Services. I should begin by saying that it was my office that performed the study in 1989 that is often quoted in connection with this law, and what I have come here today to discuss with you is the basis for that study as well as subsequent studies performed by others, hoping that in this presentation we can sort out some of the notions that may be attributed to scientific research as opposed to purely anecdotal kinds of evidence on the subject.

The study that we performed in 1989 was a study that was requested by the Congress. It was mandated in the Medicare Catastrophic Coverage Act of 1988, and it was completed on May 1, 1989. It was the first nationwide study of financial arrangements between physicians and various entities. It consisted of a survey of about 4,000 physicians who were randomly selected, and it focused on 3 kinds of entities—independent clinical labs, independent physiological labs, and durable medical equipment manufacturers.

The result of our studies were that 12 percent of the physicians that we surveyed were found to have an ownership interest in these entities, and 8 percent were found to have compensation arrangements. On the reverse of that, 25 percent of the clinical labs, 27 percent of the independent physiological labs, and 8 percent of the durable medical equipment companies were found to be owned in part By physicians.

As far as referral was concerned, we found that the patients of physicians who had an ownership arrangement received 45 percent more independent clinical lab services, and you can see this on the chart over here where there were on average 9.8 percent services for patients of owning physicians and only 6.7 services per individual for all patients.

The smaller bars on the right refer only to services that were performed through independent clinical labs. The one on the left is for all laboratory services, which could include outpatient departments of hospitals, for example. The difference is probably greater than that as expressed in the bars because the base includes all physicians as well as including those who have an ownership interest whereas the orange bar is just those with an ownership interest so the real difference between referrals by owners and nonowners is probably a little bit greater than you see on the chart.

We found that 13 percent more services were provided to patients by physicians who had an ownership in independent physiological labs, and we found no difference in the number of services provided by owners of durable medical equipment companies. In the case of the independent clinical labs, we also analyzed what the cost to the Medicare Program was of these different referrals. We did not perform a similar analysis for the independent physiological labs or the durable medical equipment, so in the case of durable medical equipment we do not know whether patients received more expensive equipment, for example, from physician owners than otherwise.

Regarding the cost to Medicare, at the time of our study, which was based on 1987 data, it was a cost of about $28 million, and for the purpose of this testimony we analyzed what the effect would be today just looking at the growth in Medicare labs, and for independent clinical labs alone it exceeds $100 million in today's dollars.

If you were to add on all other labs, I would have to take a guess, but I would say that it would probably put it up in the $150 million range, and in making the projection we did not take into account the fact that there has been an increasing rate of ownership as well. It assumed the rate of ownership when we did our study.

Since the time that we did this one study, nine other scientific studies have been performed using fairly large databases, some on a national basis, some in States. There have been studies done in Boston, Florida, California, and several on a national basis. These studies have been published in the New England Journal of Medicine, the Journal of Medical Associations. In general, these studies found patterns very similar to what we found, particularly for clinical labs, radiology services, especially for MRIs and CAT scans, physical therapy and rehabilitation, radiation therapy and psychiatric evaluations.

In general, the studies showed more services, higher prices, services not performed in underserved areas, and some studies showed no difference in patient characteristics, or physician specialty or in the sophistication of the test performed. In some cases, the subject showed that differences were greater for higher cost services, and in some cases the proportion of ownership was higher among physicians who were in a position to refer than otherwise.

To my testimony, I have attached a synthesis of these various studies which I hope will be helpful. Given the purpose of this hearing, we tried to find out whether any studies had been done about the effect of arrangements in managed care settings, and I can tell you that in looking at the studies, none of them addressed this particular problem as such.

One of the problems that has already been mentioned several times in this hearing is that the term, "managed care," is simply not very well-defined, and we will probably have to draw inferences ourselves of the effect of these arrangements in the various settings.

Let me just give you two really quick examples, if I may. Everyone knows and has already mentioned the case of the prepaid health care, and I think we have a pretty good agreement that this does not contain those incentives for increasing the number of serv-

ices because of referrals. Other kinds of care that are often called managed care might be preferred provider organizations, case managers, preauthorization/gatekeeper arrangements, postpayment utilization reviews with financial penalties for people who overutilize or overrefer.

Just to take one, the preferred provider organization, and to walk through it for a moment. In this case the physicians in the network might be provided a discount or accept a lower rate of pay than physicians not in the network. I think it stands to reason that the fact that a physician is receiving a lower rate of pay for his services does not mean that the incentive to refer to a self-owned facility would be any less just because the physician is in a preferred provider organization.

Similarly, if you look at the other arrangements we would have to work our way through them carefully and distinguish carefully for each of these. I think that is a fair summary, sir, of the studies that have been done. In listening to the testimonies of the people who have preceded me, I think we all recognize that there is a very complicated and delicate task before the Congress and before the members of the medical profession.

In reflecting upon the way that I could be of greater service to the Committee, I feel that it is probably in terms of answering questions regarding the study since I have heard some questions there and in terms of the various aspects of enforcing the law, although, of course, I would be happy to answer the questions on any subject that you wish.

[The prepared statement and attachment follow:]

TESTIMONY OF GEORGE F. GROB
DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS
OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning Mr. Chairman and members of the Subcommittee. I am George F. Grob, Deputy Inspector General for Evaluation and Inspections of the Office of Inspector General (OIG) in the Department of Health and Human Services. We appreciate the opportunity today to address the problem of self-referral in the health care industry.

Created in 1976, the OIG is statutorily charged to protect the integrity of departmental programs, as well as promote their economy, efficiency and effectiveness. We meet our challenge through a comprehensive program of audits, inspections, program evaluations and investigations. In FY 1994, we were responsible for 202 successful criminal prosecutions and 1,334 administrative sanctions imposed against individuals and entities who defrauded or abused the Medicare and Medicaid programs or their beneficiaries. In addition, we obtained $185 million in civil monetary penalties in FY 1994 and accrued more than $5 billion in program savings.

Much has been learned since 1989, when the issue of self-referral became a matter of attention by this committee and the Congress, and by our office. We believed 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 profit motive can insinuate itself into patient care and possibly lead to inappropriate use of medical services. Now we are even more convinced of this. If unaddressed, this situation can result in higher costs to patients, insurers, and the Medicare and Medicaid programs, and can prevent patients from receiving the best quality of care. It can also expose patients to unnecessary medical procedures.

At the same time, 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 more appropriate development of modern medical care systems. I hope that the results of our studies and those of others who have addressed these concerns will be helpful to all of you in this effort. I will summarize our work and related studies, and then discuss briefly the implications of our findings for managed care.

Concerns About Self-Referral

The overall concern about self-referral is that health care decision making should be free of the profit motive. Patients want to be assured that financial interests are not affecting physician decisions about their medical care. This concern breaks into three basic categories: 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 no profit motive. 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 sharing profits with 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.

Before the enactment of section 1877 of the Social Security Act, the only statute available to attack the problem was the Medicare and Medicaid anti-kickback statute (42 U.S.C. §1320a-7b(b)). This is a broadly-worded, criminal statute which requires proof of intentionally 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.

Inspector General's Report

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 subsample 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 referred 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 demonstrated 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 the New England Journal of Medicine and 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 are 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.

These studies support the proposition that some physicians respond to financial incentives. This may account for some of the growth in recent years of physician investment and ownership in medical service companies.

Federal Legislation Prohibiting Medicare Payment for Self-Referred Services

Based in part on the results of our study, in November, 1989, Congress passed Section 1877 of the Social Security Act (sometimes referred to as the "Stark Amendment", or "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 response to problems of self-referral in a broad range of services demonstrated by the additional studies cited above, 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.

Managed Care

Many of the exceptions are specifically designed to allow for the development of managed care plans, integrated delivery systems, and new health care networks which link hospitals and doctors. Because of the importance of these emerging innovations in health care delivery, some groups have argued for the creation of a new, broad exception for "managed care."

One of the problems with this idea is that the term "managed care" is not well defined. Some understand it in the narrow sense of a health maintenance organization (HMO), in which services are prepaid by the patient through a fixed monthly fee. The Stark amendment already allows an exemption for this kind of arrangement in the Medicare program, where conditions of participation and rules of financing are well defined. This exception is appropriate for at-risk HMO's, because this structure removes from the physician the financial incentive to refer patients to other service providers. Typically, the physician does not stand to gain any profit from referring the patient for a laboratory or other medical services owned by the physicians in the HMO network.

Others use the term "managed care" in a much broader sense. For example, it can be applied to a preferred provider organization (PPO), to the use of a "case manager," to pre-utilization or "gatekeeper" functions, or to a system of post-utilization review with financial punishment for those who over-prescribe ancillary services. Financial incentives in these arrangements are more complex, but in most of them the physician is not truly shielded from the influence of profit making on referral decisions.

Consider the PPO arrangement, for example. Here, the physician and ancillary service providers agree to accept a lower price for their services than those providers who are not in the network. But a physician who is an owner of a clinical laboratory which is part of the network would still gain a profit by referring patients to his or her own, rather than some other, laboratory. Hence, no exception to the self-referral ban would be appropriate. Upon close examination, it may be found that none of the arrangements called "managed care" really shield the physician from the profit influence of self-referral other than the prepaid HMO arrangement.

However, as noted earlier, many of the exceptions already allowed in the Stark amendment provide flexibility for managed care providers, even in the broader meaning of that term.

For example, there is an exception in the statute for physician ownership interests in hospitals. There is only one condition, and that is the ownership interest by the doctor must be in the whole hospital itself, not in any division or branch of the hospital, such as just the surgical wing.

Another exception allows for payments to employees, with three requirements. The payments to the employee must be for identifiable services, the amount of the payment must be consistent with fair market value and be commercially reasonable, and the amount cannot take into consideration the volume or value of referrals by the doctor to the entity. There is also a provision which allows for the payment of productivity bonuses. These are permissible if the amount of the bonus is based on services personally performed by the physician, as opposed to services that the doctor orders for someone else to perform.

There is an exception for personal service arrangements, such as consultation contracts. The agreement must be set out in writing, and must cover all services between the parties. The services cannot exceed those that are reasonable and necessary. The agreement must have a minimum one year term. The compensation under the agreement must be at fair market value for services rendered, and cannot take into account the volume or value of any referrals. The exception also allows the existence of withhold pools such as those often used in managed care arrangements.

The law allows for payments by hospitals to physicians without restriction, as long as the remuneration "does not relate" to the provision of designated health services at all. In other words, a hospital can hire a physician to operate its utilization review program with no restrictions specified in the law.

Payments for physician recruitment are permitted -- for example to get them to relocate to the geographic area of the hospital. There are only two requirements -- that there be no requirement in the contract that the physician make referrals to the hospital, and any payments not be related to the volume or value of referrals.

There is also an exception for so-called "isolated transactions," which explicitly applies to the purchase of a physician practice, either a solo practice or a group practice. The price must be for fair market value and be commercially reasonable. The price cannot be related to the volume or value of referrals.

Finally, there are other exceptions for leasing of office space, leasing of equipment, etc. All these exceptions leave room for some flexibility as they attempt to balance control of self-referral with avoidance of unnecessary controls on the industry.

Conclusion

The research on physician behavior indicates that the profit incentive does increase the rate at which physicians order 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 cost to the Medicare and Medicaid programs and their beneficiaries and could adversely affect quality of care. Any revisions to the statute intended to allow the formation of health care networks should, at the same time, discourage the existence of inappropriate incentives for physicians to order ancillary services.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

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 percent 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 percent 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 percent and the number of x-ray films per visit by 16 percent. The total charges per month, adjusted for inflation, grew 20 percent, 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, Noehter 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 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 JM, 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 60% 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 difference 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 analyses 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 approximately 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 Mr. Grob.

Mr. McCrery, do you wish to inquire?

Mr. MCCRERY. Thank you, Mr. Chairman.

Mr. Grob, just a question about your figures on the Medicare cost of laboratory self-referral. In 1995 you have $103 million—explain to me again how you derived that figure.

Mr. GROB. It is a conservative estimate. What we did was we assumed the same proportion of ownership and the same proportion of self-referral as in 1987, and then we simply tracked out the growth of Medicare payments for independent clinical lab services over that period of time, performed an index, and multiplied it by the original base. The reason it is conservative is because the original proportions are probably larger now.

Mr. MCCRERY. OK. If we were to completely eliminate self-referral, let's assume that every one of those instances of self-referral were bogus, they were fraudulent, OK, and we, by this law, were able to stop every instance of that abuse, and so our total savings would be $103 million?

Mr. GROB. That would be for independent clinical labs. That corresponds to the charts on the right, which is a smaller subset. We are unable to estimate from the databases the effect of all lab services. If you want a professional guess, I would say based on the proportions in the other charts, it is probably an additional 50 percent, so we would probably be looking at $150 million.

Then if you were to work into it the rise in ownership over this period of time, it would size it up somewhat, so you might be approaching $200 million. And then, of course, this is only for the clinical labs. It does not touch the other elements in the bill.

Mr. MCCRERY. But again that is assuming in every instance the referral was fraudulent, it was not needed and it was just a physician practicing fraud.

Mr. GROB. Not to reach the intent of the individual, but your point is nevertheless well taken. These would be payments that under the Stark bill would not be made because they were referrals made by a physician who has an ownership in an entity, so laying aside the motive or the need, things of this nature, you are correct.

Mr. MCCRERY. You would also have to assume that these referrals would not be made to someone else if you are going to say we would save this amount of money.

Mr. GROB. That is correct.

Mr. MCCRERY. That the referral would not be made at all if you are going to save this.

Mr. GROB. That is correct.

Mr. MCCRERY. So, over a 5-year period, Mr. Chairman, if we make all of those outlandish assumptions, we are only looking at about $750 million in savings. While that is a lot, in the context of what we are looking at saving for Medicare over 7 years, it is not a whole lot.

Chairman THOMAS. If the gentleman would yield, if you are asking me for a response, it seems to me that the assumption that none of the tests were taken because they were needed is an enormous hurdle to overcome.

Mr. MCCRERY. Sure.

Mr. GROB. Mr. Chairman, could I address that because I have heard you asking that question to the previous panel, and you did relate it to the studies. I can speak most conclusively for the studies we did, but I did try to examine the other studies that were done, so let me try to address other studies.

I will agree in our study we certainly did not reach that question. So, I would like to give two examples from the other studies. There was one national study that did look at imaging services and showed a much higher utilization and it was nationwide, and in that case they were able to detect whether there were any differences in the characteristics of the patients or in the specialties of the physicians or in the sophistication of the tests that were given, and they were able to prove that there were no such differences.

Now, there is another study, I think, that is even more revealing, and you will have to draw your own inferences. It was a study done in Boston. It was a very small case study. It reached the question of compensation arrangements. There were walk-in ambulatory services in which physicians were paid about $24 an hour in 1985 to provide services to patients who walked in, and along that time they decided to change the compensation arrangement to allow for an alternative where the physician would receive 25 percent of the first $25,000 of payments and then 15 percent for amounts above that.

At the end of the month, one could see which method would give the greater payment. They were able to find 15 physicians who were with that organization before that change was made and were still there a year after the change was made, and they were able to collect information about the billings of those physicians during that period, and there was a very substantial increase in the billings and the services provided by those physicians simply from the 1 year to the next.

Now, during that period of time, the facilities were the same, the services were the same, the patient profiles were the same, and the physicians were the same. The only thing that was different was the compensation arrangement.

Now, again, I think everyone will have to draw their own conclusions, but here is a case where the only difference was in the compensation arrangement. I do not know that there are many other studies that are that precise in distinguishing that difference, and I will say that the study was very small, and so, again, you will have to draw your own conclusions.

Mr. MCCRERY. Thank you, Mr. Chairman.

Chairman THOMAS. Mr. Stark.

Mr. STARK. Mr. Grob, as I recall, Mr. Kusserow was the predecessor in your department when all this started—the problems that you all were having with prosecuting. In other words, what we lacked, when I think he came to us and suggested we change the law, was that you could not find intent.

We had all kinds of records of people overutilizing and getting referral fees, but they were couched in a kind of legal and joint venture type arrangement where the Inspector General could not determine intent and could not prosecute. Further, we had some problems trying to get requirements that each physician list, when

they report, when they request Medicare payment, whether there was any involvement; or whether there was any ownership. Would it be a huge difference in the way we now reimburse—I think that something like 99 or 95 percent of all Medicare reimbursement is done electronically.

Mr. GROB. I am sorry, sir, I could not hear.

Mr. STARK. Done electronically. I believe it is a pretty high percentage; is that not correct?

Mr. GROB. Yes.

Mr. STARK. If, in fact, because the entity in which a physician may have an ownership interest and from which it may receive payment, he or she may receive a referral, is also arguably getting paid by Medicare. Would it be beyond the strand so forth of our communication age to document whether the physician had an ownership interest so that you could compare the data in terms of utilization. We could probably stop making all these studies.

Now, the difficult part was if you saw an abuse, statistically, how would you prosecute them or get them to stop? Maybe just by exposing it. I guess what I am getting at is would it help for us in the future to have this data, which would be confidential to HCFA. Would that be useful?

Mr. GROB. I think there are certain categories of entities for which it would be practical to make a computer link, for example, in the case of the independent clinical labs, a straightforward matter. Other arrangements——

Mr. STARK. Where it is available.

Mr. GROB [continuing]. Would be a little bit more difficult. Perhaps this is a good opportunity to reach a question implied by the one you asked me and given to previous witnesses about the utilization review. I would have to agree that taken one at a time I do not think that any of the studies that have been done have ever demonstrated that the particular service was unnecessary or inappropriate.

It is only in the global sense and inferring from what has happened in the studies that same problem would occur as an administrative matter so that if the Health Care Financing Administration were put in a position of having to profile physicians, what you would be asking is for administrators at the Health Care Financing Administration and their carriers and contractors to look over the shoulders of physicians and second guess whether the physician had, in fact, made an appropriate——

Mr. STARK. They would not like that, would they?

Mr. GROB. Well, some of the previous witnesses said that they thought that approach might work. I simply wanted to alert the members of the danger inherent in that.

Mr. STARK. Your future request, I presume, to the Congress will be based not on whether or not you think it is ethical or better for the system to allow referral compensation or not, but whether it helps you enforce laws and end the practice or punish or get convictions if that is what you have to do.

Your interest in this legislation, I presume, is not to change doctors' practices or to change the practice of how people organize group medicine, but it is to be able to enforce the laws that we pass. Is that not true?

Mr. GROB. I do not think there has been anyone who has been in this room today that does not wish the whole thing were simpler. We certainly have a great deal of problem using our current enforcement authorities. The antikickback statute is extremely difficult to prosecute because intent needs to be shown, and——

Mr. STARK. You are talking about the 1976 law?

Mr. GROB. Yes, and physicians or others who participate in these things never do it in a straightforward matter. The schemes are always quite complicated, so it is difficult to ferret out and it is just very, very difficult for us to enforce.

Mr. STARK. Are you going to bring us suggestions? Is that part of your office duties?

Mr. GROB. We have from time to time brought suggestions on changes particularly relating to the need to prove that someone knowingly and willfully violated the law and things of this nature.

Mr. STARK. Will you bring us suggestions in the future, the immediate future? Because I think that the Subcommittee is curious to know what should be done, and it would be helpful, I think, to hear. You are the cop on the beat. If there is a law that should be enforced, you have got to do it.

Mr. GROB. I think we can bring some suggestions probably for the current enforcement authorities.

Mr. STARK. Thank you.

Chairman THOMAS. Does Mr. Ensign wish to inquire?

Mr. ENSIGN. Thank you, Mr. Chairman. On your chart when was that study done?

Mr. GROB. It was done in May 1, 1989. It was based, as you can tell, on 1987 data.

Mr. ENSIGN. OK. Have there been any studies to see whether that was accurate? Have you been enforcing the law at all?

Mr. GROB. Let me take the questions one at a time. The other nine studies that I have mentioned that were scientifically done were done after 1989, mostly during the late eighties and early nineties, so there had been studies done after this one that have had results that are very consistent with the results that we have found here, so that is the answer to your first question.

As far as enforcement is concerned, we have not enforced the ownership law because the regulations are not out. Now, we believe that the law, as it stands, could be enforced without regulations, and if a case were referred to us, we would feel obligated to investigate it.

Mr. ENSIGN. Do we have any information on whether physicians have already divested themselves so that the law has had that effect up to this point, has it?

Mr. GROB. No, sir, I do not have that information.

Mr. ENSIGN. There are States obviously with this law on, Nevada being one of them. Have there been any studies to see whether the laws in those States have been effective in eliminating fraud?

Mr. GROB. There have been reviews and the results are quite mixed. The studies are difficult to do because the State laws are quite varied in the way they are structured. Some are much stronger than others, some are weaker than others. I can simply say that the results are quite varied.

Mr. ENSIGN. In the ones that have strong laws, are they saving a statistically significant amount of money?

Mr. GROB. Could I get back to you with more precise information?

Mr. ENSIGN. If we already have States that are doing it out there it would seem to me that would be a good place. States that have a large population, so we can get some statistically significant information from a State.

Mr. GROB. We do have information about State laws. I am giving you my impression of the studies. In previous briefings, our position had always been that the results were quite varied. What I cannot do now is reach into my mind and pull out the particular instances.

Mr. ENSIGN. The other comment that I guess I would make, you mentioned that some of the studies have looked to see whether there was a difference in expertise on referrals. Just from my own personal experience when you become aware of a technology because you are investing in it, you understand it, just common sense tells you that you will understand that technology more than somebody who has not invested in it because you have something invested in that now.

I mean, just common sense tells me that a physician that has invested in a particular type of technology is going to understand the application of that technology, and that maybe a lot of the reason that these things are being referred is simply because the physician is more aware that this technology can be applied to a certain disease, a certain situation, a certain set of clinical situations, and these referrals may be because patients get better care.

Mr. GROB. Yes, sir. It is very difficult to get inside people's minds and understand it, and I think that there is room for lots of interpretations. What I was hoping to do here was, in fact, to make it possible for you to see what the data was and what the results are. I think—

Mr. ENSIGN. But when we are interpreting the data and the results, we have to look at underlying assumptions. Anytime we are looking at data, it does not mean anything unless you take all of the variables into play.

It is like when you are evaluating a study in medicine, sometimes we see the increase of a disease simply because physicians are more aware of what to look for, it does not mean the disease is increasing. I mean we have to know that as an underlying assumption. If we do not understand this as an underlying assumption, we may look at this and pass bad laws because we have a wrong underlying assumption.

Mr. GROB. I could not agree more, sir, that all these things need to be considered. I think, if I may just add to the other one, I think another assumption is that physicians are like the rest of us, human beings, and it is quite possible that the profit motive might well insinuate itself into the medical decisions, but the other reasons also need to be considered, and I think that Congress has a difficult set of decisions to make here.

Mr. ENSIGN. Are there any States that have the sunshine laws that we are talking about, the disclosure?

Mr. GROB. I believe some of them do. Now, if I could address the disclosure thing here, I think that there probably is a good point to that, but I would say, as well, that it is probably a great tribute to the American medical profession that patients have so much trust in their physician so that the disclosure to the patient of ownership may be seen by many patients as an endorsement of the service, so there is that to consider as well.

Mr. ENSIGN. OK. Thank you, Mr. Chairman.

Chairman THOMAS. Thank you, Mr. Ensign.

Mr. Grob, attached to your testimony is the self-referral studies, A through J, I believe. You indicated one of them was a national study. The other one was the small one that you had some comfort in terms of the comparability. Which of the others, if any, out of the 10 that you have listed provide some kind of a corrected factor for the case mix or the severity of illness of the various patients?

Mr. GROB. Let's see, sir, if I can try to get some of them. The study B is the one that I mentioned was the case in Boston. That is the small one there, and because of the way that the study was structured does take that into account, the next one was study C, and that is the one that I was referring to.

Chairman THOMAS. That is the broad national one.

Mr. GROB. Yes.

Chairman THOMAS. Do any of the others, then, have a case mix or severity of illness corrective factor?

Mr. GROB. I would have to go back and examine that much more carefully. I will be happy to do that.

Chairman THOMAS. I appreciate it. I believe the answer is they do not. But I would be willing to stand corrected.

[The following was subsequently received:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAY 24 1995

The Honorable William M. Thomas
Chair, Subcommittee on Health
House Committee on Ways and Means
House of Representatives
Washington, D.C. 20515

Dear Mr. Thomas:

I am writing to follow up on two questions that were raised at the May 3, 1995, oversight hearing regarding physician self-referral held by the Subcommittee on Health, House Committee on Ways and Means. I promised to provide answers for the record.

First, Representative Ensign asked if I was aware of any studies that evaluated the effect of the various State laws on the practice of physician self-referral. We had actually conducted an analysis of State laws as part of the study which we submitted to the Congress in 1989. This was the study which I referred to in my testimony, and which I described as giving "mixed results." We found that no State had an outright ban on physicians owning a health care entity. Eleven States required a physician to disclose a financial interest to patients. Thirty six States had anti-kickback laws. Only Michigan had a law which forbade physicians from referring patients to entities in which they have financial interests.

The overwhelming majority of our State respondents said that they were unable to monitor for compliance of existing laws. This made it impossible for us to evaluate how effective these laws would be if they were enforced. Surprisingly, Michigan had the highest average of laboratory services per Medicare beneficiary, despite it having the strictest law. However, the fact that we found laboratories in which Michigan physicians had an ownership arrangement and to which they were referring Medicare patients indicates that the law was not being enforced.

I am not aware of any other studies on this subject. I have enclosed a copy of our study for your information. However, I must caution that State laws may have changed since we published this report in 1989.

Second, you asked whether any of the studies cited in my testimony took into account factors such as case mix, medical necessity, or other factors (other than ownership interests or compensation arrangements) that may explain increased utilization. I noted at the hearing that two of the studies took such factors into account: (1) 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); and (2) 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, Noehter M: New England Journal of Medicine, 1990;322;1604-1608).

I would like to call to your attention two additional studies cited in my testimony that also take such factors into account. (Copies enclosed.) One study concluded there was no reason to attribute the differences between joint venture and non-joint venture freestanding physical therapy and rehabilitation facilities to the health status of the population. The study found that visits per patient were 39 percent to 45 percent higher in facilities owned by referring physicians and that both gross and net revenue per patient were 30 percent to 40 percent higher in such facilities. Percent operating income and percent markup were also significantly higher in joint venture facilities. "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).

In another study, the authors compared the patterns of physicians who referred patients to facilities of which they were owners to patterns of physicians who referred patients to independent facilities. The study showed that California physician-owners of MRI facilities ordered medically inappropriate MRI scans at a rate about one-third higher than physician non-owners. A prospective precertification program was used to determine whether the referrals for MRI scans were medically appropriate. As part of this program, an independent utilization-review firm gave an opinion regarding medical appropriateness based on the medical documentation of patient's injuries, conversations with the referring physician, and criteria established by board-certified physicians. The study estimated that where referring physicians own MRI facilities, the costs to the health care system of this expensive technology goes up by 31 percent. "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).

I appreciated the opportunity to testify about our 1989 report on physician self-referral as well as nine other studies that have appeared in the professional literature on this topic. I hope this additional information will be helpful to you and other members of the Subcommittee as you consider the complex issues relating to physician self-referral. I would be happy to provide you and your staff with any additional information you need and stand ready to consult with you and your staff regarding any legislative proposals to amend or revise the physician self-referral.

Sincerely yours,

George F. Grob
Deputy Inspector General for
Evaluation and Inspections

Enclosures

cc: The Honorable John Ensign

Just let me say, Mr. Grob, I have done a little bit of looking at methodology in my previous life on behavioral sciences studies. And at the end of your statement to say, "draw your own conclusion," I am not used to having a Rorschach test as the conclusion of a study.

When you say that the sum of the studies is greater than the studies themselves, that somehow you cannot find it individually, but when you look at them in total, you clearly see what is going on, I mean, to me that is a Rorschach test.

You see what you want to see, and I am telling you, I perhaps do not see what you want me to see, unless the test is structured in a way which proves relatively specific points. In your discussion with Mr. Stark, enforcement to me is a means, not an end. And when you talk about intent getting in the way of enforcement, it really does make me believe that you have already drawn the conclusions—studies do not show it, but you know it is there, and that trying to prove intent is extremely difficult. So, let's set intent aside.

We can now go out and enforce my already preconceived notion about what is going on out there, bolstered by the simple fact that here is a physician and here is involvement. Draw your own conclusions, do not encumber me with intent. But I know what is going on. That, frankly, is a relatively frightening conceptual framework, which I drew from the way you voluntarily discussed the work that you have provided and your response to Mr. Stark's questions about enforcement. And that is where we are today.

I was very upset, especially with the Florida study on the MRIs, For example, I kept asking the questions, did you do anything to examine whether or not the patient problem was solved quicker, was the diagnosis more accurate, was the total cost package cheaper? I think these questions ought to be the driving aspects here.

The answer to those questions was no, no, no. All we did was look for the relationship. And if you find a relationship in your own words, draw your own conclusions. I have a very difficult time with that kind of methodology being the basis for this kind of a law when you throw intent out the window.

Now, if that is the sole basis for our having moved this legislation not once but twice, then I think you can understand the reason for this hearing and subsequent hearings if necessary. Frankly, I just do not draw my own conclusions in the same way that apparently you do. I look at each individual study and I find each individual study almost fundamentally flawed in its methodology, and therefore in sum I find the package relatively less helpful in drawing a conclusion. So, we have some, I think, fundamental problems here in terms of laying groundwork, especially if you are going to set aside intent.

If you had brought intent into the mix, I would have a little higher comfort level. But, you have told us that in other areas of trying to move forward, intent gets in the way of enforcement. So, we do away with intent. When you talk about that, it seems to me that enforcement becomes an end, rather than a means, and I am very concerned about that kind of a draw-your-own-conclusion mentality.

You want to respond?

Mr. GROB. Yes, sir, if I may respond.

There were two areas there. One had to do with the accumulation from several studies and how it might be interpreted. The other one had to deal with intent. Let me talk about the intent first, if I may.

The intent was made in reference not to this law, but it was made to the antikickback laws. And the requirement to prove that someone intentionally violated the law is rather unusual, if you will. When a crime is committed, usually the burden of proving that the person intended and willfully intended to violate the law is a prosecutorial——

Chairman THOMAS. Excuse me. Are you equating the ownership of a piece of medical apparatus with a crime?

Mr. GROB. No, sir. The application to the antikickback law——

Chairman THOMAS. I understand that. But, transferring it to another area now, the mental set of trying to prove intent in an area of preagreed upon and prearranged criminal activity.

Mr. GROB. Yes, I wanted to be clear on that. The question I was answering there had to do with the difficulties of enforcing the antikickback law, sir, not this law. It is not related to this one. The question——

Chairman THOMAS. But this law does not have intent in it.

Mr. GROB. That is correct.

Chairman THOMAS. My understanding was one of the reasons it wasn't included was because of the difficulty to include cases in previous experience, which was the kickback law. Do you think this law would be improved if you put intent into it?

Mr. GROB. No, sir, I think it would be more difficult to use.

Chairman THOMAS. Why would not it be improved if you included intent?

Mr. GROB. It is——

Chairman THOMAS. Because it would be harder to enforce?

Mr. GROB. It would be very difficult to prove. Let me—let me—I do not mean to reverse the question, but if I could just state it hypothetically, and it goes back to the question of the utilization reviews. If you saw a pattern, as some have been indicating here where there was a much higher level of utilization among physicians, if you had a system that tried to eliminate any abuse by making it necessary for administrators to prove that the services were unnecessary one by one, or that the physician or other health care practitioner had the intention to rip off the system, it would be just a very impractical way to administer the law.

Chairman THOMAS. I understand that. But the study that you are asking me not to carefully examine the structure of, never looked at the efficacy of the decision, the comfort of the patient in terms of correct diagnosis earlier, or whether or not ultimately the whole procedure was more cost effective than was otherwise the case.

If you do not have those kinds of parameters in a study, what you have done is simply connected the dots. And then as you said, draw your own conclusion.

I will have to tell you that that is a level of proof, one, I am not familiar with; two, I am very uncomfortable with removing intent from the equation because it makes enforcement too difficult. That

is part of the reason we are examing this process. The other part, of course, is that it is occurring at a time which perhaps makes it far more difficult, creates a chilling effect on some positive arrangements that some of us think actually will wind up saving far more money than your chart indicates would be saved if every laboratory test in the United States had no rational basis for being used and that we eliminated them all. That is, obviously, overstating the parameters of that particular chart, but that is in part where we are being led.

Mr. GROB. Sir——

Chairman THOMAS. You can respond, but I will respond back. So, to save time for everybody, let's just leave it at that. I expect to be convinced by each study, and the cumulative weight of the studies never ever exceeded the sum of the studies. Because if they do, you are bringing something to those studies that is not there.

Mr. GROB. Did you wish me to respond, sir?

Chairman THOMAS. You can see it. Somebody else might see it. But, you cannot prove it to somebody else, unless they accept the same assumptions that you do in drawing your own conclusions. Unfortunately, you have not been able to convince me that the conclusions are the same, because frankly, I can come up with a number of other very viable, very rational decisions based upon the evidence. That is not enough to put a chilling effect on an area that we need a lot of positive dynamic change in. And, that is why we are looking at the law.

Thank you very much.

The gentlewoman from Connecticut.

Mrs. JOHNSON of Connecticut. Thank you.

I have been very interested in the issue of the pace of change and rational law and regulation. The two studies you point to in which severity was considered, are two of the three oldest studies that you cite. They are published in 1990, which means that their data was collected in the preceding 2 to 4 years, correct?

Mr. GROB. Yes.

Mrs. JOHNSON. So, their data at this point is 6 to 10 years old?

Mr. GROB. That is correct.

Mrs. JOHNSON. Right. I think that is important to put on the record. Because it simply makes them almost irrelevant. The studies that you point to as more recent, if I understand it, did look only at volume and referral. Is that correct?

Mr. GROB. Congresswoman, I would like to examine those more carefully. In preparing for this, I tried to pick out from the nine some of the examples that would show the intent and I was very assiduous in doing that. I do not review each and every one of them for that purpose. I do not want to say that none of—not intent, excuse me, but the severity of the cases. So, I——

Mrs. JOHNSON. But your process does not consider appropriateness of care?

Mr. GROB. I am sorry, which process?

Mrs. JOHNSON. These studies do not look at appropriateness, they just look at who made the referral, to what facility?

Mr. GROB. That is correct.

Mrs. JOHNSON. Yes. I think that is just very important to put on the record. I assume your office will be eventually overseeing a provision now that HCFA is including this in its manual.

This is not a provision driven by law. It is not a new regulation, but it is going to have the force of law. And it will be in their manual and it limits the panel of tests that any physician is allowed to order to 12, and any test over that is going to have to be individually documented. This is going to increase costs not only in terms of physician time, but it is going to increase costs because fewer tests are going to be batched, and so the costs of the additional extra tests are going to be higher.

Now, when your office looks at this, as you will surely be asked to look at in a few years, you will look at appropriateness of the test, at the cost of the test, at total care to the patient, at the impact on diagnosis?

Mr. GROB. We will do our best to answer any questions that are presented to us as we always have in the past.

Mrs. JOHNSON. But traditionally, you have only looked at how many more tests were ordered from the panel.

Mr. GROB. There has not been much tradition here at all, Congresswoman. We did the one study and have examined the others.

Mrs. JOHNSON. Well, actually, the knowledge about how to look at quality and volume is fairly recent. So, that is one of the problems, your studies are not as useful to us as they might be, because they do not take advantage of more recent developments.

Mr. GROB. Could I comment briefly on the timeliness of the studies, since you never asked me, but you did raise the point about the timeliness?

Mrs. JOHNSON. OK.

Mr. GROB. In the field of conducting studies like this, it is virtually never possible to be current. The databases are almost always several years old. And a danger that we all face is sort of saying waiting until we have the absolutely definitive study before action is taken to correct a problem. Again, much judgment is needed, but I would never want to promise you more than can be delivered.

Mrs. JOHNSON. I appreciate that, but I think it is important for the record to show that it takes a couple years for you to do it, that the data takes a couple years to develop. So, almost always our data is 3 to 6 years old. And I think that is important.

In your experience from watching these things, do you think an exemption for those systems in which, by virtue of the structure of their reimbursement processes, there is no longer any likelihood of referrals being linked to profit? Do you think a blanket exception of those systems would be reasonable?

Mr. GROB. I think that is perhaps the best principle to use in considering any exemptions which are proposed. Putting that one into practice is difficult, but I think that is the key, the key matter.

Mrs. JOHNSON. Would you think it logical for this Committee to consider that proposal that was made by an earlier panel?

Mr. GROB. If there were a practical way to do it, I would think that would be a key principle to use.

Mr. JOHNSON. Thank you.

Mr. GROB. Mr. Chairman, I would like to clarify one thing I said, and it is not to engage in a back and forth with you. I hope you did not construe my remark about drawing your own conclusion to be one in which I thought that the conclusion was so obvious that it was a rhetorical question. I did not mean to put it to you in that way.

I was trying to do my best to distinguish here for you the matters on which the data did provide firm evidence from those that did not. So, I hope you would understand that that was my intention in that case.

Chairman THOMAS. No, Mr. Grob, I took it I think in the way it was intended, and that is on the merits alone, these studies do not prove the conclusion you arrived at and you have to draw your own. My conclusion is different than yours.

I would like to be convinced. Timeliness of studies and meaningfulness and usefulness of studies are two different things. You have met neither of those, in my opinion.

Thank you.

Mr. GROB. Thank you.

Chairman THOMAS. The next panel consists of Dr. Wilson, Dr. Tice, Mr. Kershner, Mr. Mentz, and Dr. Strickland.

As I have indicated to the other panels, if you have any written testimony, it will be made part of the record without objection.

If we might begin with Dr. Wilson and just move down the panel, you can inform the Subcommittee in any manner you see fit.

Dr. Wilson.

STATEMENT OF CECIL B. WILSON, M.D., MEMBER, BOARD OF TRUSTEES, AMERICAN SOCIETY OF INTERNAL MEDICINE

Dr. WILSON. Thank you, Mr. Chairman.

My name is Cecil Wilson. I am a physician in solo practice in internal medicine, Winter Park, Florida. I am also a trustee of the American Society of Internal Medicine.

In recognition of the role physician office labs play in providing high-quality, convenient, cost-effective medical care to patients, OBRA 1989 exempted physician office labs run by solo practitioners or group practices from the self-referral restrictions, allowing them to continue to operate. Shared labs, exceptionally common because they are practical and cost effective, would not explicitly provide an exemption.

For the last 21 years, I have shared an office lab and x-ray machine with an internist who is in a contiguous suite. The reason I have an office lab is to enhance my ability to provide good quality care to my patients by being able to obtain test results immediately while the patient is in the office. The reason I share a lab with another physician is that I, like most solo practitioners, cannot afford such a facility by myself.

My office lab does not differ in the way it operates from office labs run by group practices or solo practitioners on their own. My lab provides in-office testing services to my patients. I directly supervise this testing. I do not do tests on other physicians' patients. I do not derive income from any test done for my lab partner's patients and I bill only for work done for my own patients.

The law as presently written provides me and my patients with no happy choices. I can close my lab, losing that service for my practice, or the other internist, and can each have our own lab, and I would say that even if we could afford that, it makes no sense. Our office doors are 24 feet from each other, and there is just not room for two labs in that building.

The other option is for us to form a group practice in order to qualify for the group practice exemption. This would require us to completely merge our professional lives, our pension and retirement plans, our billing practices and staff, as well as assuming legal and financial responsibility for each other.

Makes no sense to us to require that we reorder our professional lives in order to continue doing what we have been doing for the past 21 years, providing lab services for our patients. We are in solo practice because we value the freedom of individual practice.

Unless Congress or HCFA on its own creates an exemption for shared facility arrangements, I and others like me across the country will be forced to close our office labs, send patients across town to other labs for a test. This change will not be beneficial for my patients.

One-third of my patients are elderly and they count for two-thirds of the patient visits to my office. Many of them rely on others to bring them for their appointments, and even for those who can drive, the trip to the doctor's office requires significant effort and planning. The additional trips to an outside lab necessitated by closure of my lab will be a hardship for them and will result in unnecessary delays and diagnosis and treatment of their medical problems.

Two patients I saw last week I think provide further emphasis of the value of the lab. The first was a 66-year-old woman with symptoms of an urinary tract infection who arrived at 3:30 in the afternoon. A urine sample was obtained. I obtained a history and examined the patient. By the time I was finished, my lab tech provided me with the results of the lab, confirming infection. The patient was able to pick up her antibiotics from her pharmacy on her way home and begin treatment immediately.

The second patient, a 73-year-old man, had diverticulitis, an infection of the colon which is similar to an abscess. A blood test performed while he waited helped me to decide that treatment at home was appropriate, saving hospitalization, a $25 test instead of a multithousand dollar hospital visit.

It is urgent, that the Committee act now to protect shared physician office arrangements. We request enactment of a shared facility exception by Congress, and if necessary, steps to ensure that the Department of Health and Human Services does not sanction shared facilities before Congress has a chance to act on such an exception.

We also urge your support of some additional recommendations for changes in the self-referral laws which are addressed in our written testimony.

Finally, I would like to express my appreciation for this opportunity, Mr. Chairman, thank the Committee for its interest in this subject, and also thank Congress for its previous support of this particular issue.

[The prepared statement follows:]

STATEMENT OF CECIL WILSON
MEMBER, BOARD OF TRUSTEES,
AMERICAN SOCIETY OF INTERNAL MEDICINE

Introduction

My name is Cecil Wilson. I am a physician and general internist in solo practice in Winter Park, Florida and a Trustee of the American Society of Internal Medicine (ASIM).

My comments today will focus on problems Internists are experiencing with the self-referral laws. We believe that there is an urgent need for a limited exception from the 1989 "Stark I" law for shared in-office ancillary service facilities and a need for a number of amendments and clarifications to the 1993 "Stark II" law that took effect on January 1, 1995.

Internal medicine is the nation's largest medical specialty. As specialists in adult medical care, internists take care of more Medicare patients than any other specialty. Our members are extremely concerned that the self-referral law will have a serious negative effect on patient access to convenient and cost-effective ancillary services. ASIM does not advocate repeal of the self-referral law. Instead, we believe amendments to the law are essential to make sure it is reasonable and workable.

Shared In-office Ancillary Services

I share an office laboratory, laboratory technician and an x-ray machine with another solo practicing internist who is in a contiguous office suite; I have done so for over 21 years. The reason I share an office laboratory and x-ray machine with another solo internist is to provide convenient and cost-effective laboratory tests and chest x-rays for my patients. The ability to get test results immediately while the patient is still in the office helps me provide good quality care to my patients. Unless Congress creates an exception for shared in-office arrangements such as my own (or the Department of Health and Human Services sees fit to grant a regulatory exception) I will be forced to close down my office laboratory and send patients across town to another laboratory for tests. This change will not be beneficial to my patients. One-third of my patients are elderly. This group accounts for two-thirds of the patient visits to my office. Many of them rely on others to take them to their appointments, and even for many of those who can drive, the trip to the doctor's office requires significant effort and planning to schedule travel during less busy periods in the day when they feel safer driving. Additional trips to an outside laboratory, which would be necessitated by the closure of my laboratory, will be an extreme hardship for them, and will result in unnecessary delays in diagnosis and treatment of their medical problems.

The current self-referral law, with its in-office ancillary services exception, protects access to ancillary services provided by group practices and solo practitioners who do not share a laboratory. The law does not specifically recognize the existence of a third common type of in-office arrangement: the in-office ancillary service facility shared by physicians in different practices who practice in the same building. This puts my office laboratory and other labs like it in immediate jeopardy of being closed.

A shared facility is an in-office diagnostic facility shared by physicians who practice in the same building but who are in different practices. The shared facility is located in the same building as the physicians who share it and provides timely and convenient ancillary services such as clinical laboratory testing and x-rays to their patients. Each physician pays part of the lab expenses and bills only for his or her own patients. Each physician supervises his or her own test results. The physician does not derive any income from the referrals of any of the other physicians in the arrangement. In these aspects, the shared arrangement is no different than in-office facilities exempt from the law, specifically those facilities operated by group practices or single solo practitioners.

Shared arrangements are common business arrangements in this country because they are practical and cost-effective. The high cost of operating a quality lab or providing x-rays within the office setting is prohibitive for most solo-practicing physicians and even some small groups. I could not afford to maintain my laboratory without sharing the cost of equipment and the salary of a technician with my laboratory partner. Our expense sharing arrangement allows me to provide testing services to my patients in the most cost-effective manner possible. The arrangement is also practical. My lab partner's office door is 24 feet from mine. It makes no sense for us to have two labs in the same office space, even if we each could afford to maintain our own labs. It also

is not a viable option for me and other physicians in shared arrangements to form group practices in order to qualify for the group practice exception. Becoming a group practice entails completely melding our professional lives, pension and retirement plans, billing practices and staffs as well as taking on legal and financial responsibility for each other. It is not reasonable to expect independently-practicing physicians to form group practices with each other just to be able to continue to provide the same services they have provided patients in the past. My laboratory partner and I are in solo practice because we want to practice individually.

There have been a number of attempts to fix the shared facility problem legislatively. Congress passed a shared facility exception as part of H.R. 11, the tax bill from 1992. H.R. 11 was vetoed by then-President Bush for unrelated reasons. Last year shared facility exceptions appeared in all the major House health system reform bills, including the bill reported out of the Ways and Means Committee. ASIM supports the specific language of the shared facility exception included in the House bipartisan health system reform bill from 1994 (H.R. 5228). This exception would exempt from the self-referral ban in-office ancillary services that are furnished:

a. personally by the referring physician who is a shared facility physician or by an individual directly employed or directly supervised by such a physician;

b. by a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician unrelated to the furnishing of shared facility services;

c. to a patient of a shared facility physician; and

d. the shared facility services would be required to be billed by the referring physician.

ASIM believes these criteria will eliminate risk of program or patient abuse and will preserve this type of practical and cost-efficient delivery of patient services.

The final regulations implementing the original self-referral statute from 1989 will be published in the next couple of weeks. We have urged the Secretary to use the authority granted her under Section 1877(b)(5) of the Social Security Act to create a shared facility exception. In our view, this exception does not differ substantially from the other in-office ancillary services exceptions already provided under the law. We are concerned that the final regulation will include a shared facility exception.

It is urgent that the legislative branch take immediate action to protect shared facilities by granting an exception. At the very least, we urge Congress to take action to prevent the Department of Health and Human Services from sanctioning shared facilities until it has time to consider a shared facility exception. If the final regulations make shared arrangements illegal, I and other physicians like me will not be able to risk sanctions to keep our in-office testing facilities open even if we know Congress plans to grant a shared facility exception in the future. Access to in-office testing will be cut off for thousands of patients.

Amendments to the OBRA '93 Physician Self-referral Statute

In addition to a shared facility services exception, ASIM believes clarifications and amendments must be made to address confusing and unnecessary provisions in the OBRA 93 self-referral law.

First, the requirement that members of a group practice may not be compensated based directly or indirectly on the volume or value of referrals made by such physicians should be repealed. Not only does it interfere with the internal affairs of private businesses, but my colleagues in group practice tell me that they cannot figure out how to distribute revenue from ancillary services (if there are any after overhead expenses are paid) without indirectly taking into account the referrals made by the physician to some degree. Another problem in some cases is that ancillary services are bundled into a single payment for a particular procedure. How is the revenue for laboratory testing suppose to be separated out from other services in this case? The Department of Health and Human Services has authority under other provisions of the Medicare statute to penalize physicians who order unnecessary ancillary services without this unnecessary intrusion into the operations of private professional practices.

Second, hospital inpatient services, outpatient prescription drugs, x-rays, and parenteral and enteral nutrition and durable medical equipment (DME) provided within a physician's office should be removed from the list of designated health services covered by the self-referral ban. OBRA '93 inappropriately expanded the scope of the self-referral ban to many services integral to internal

medicine. No explanation was given to why these services were added to the prohibition. Certainly no good evidence exists to show that these services were being abused within physician practices. However, the current law makes it difficult or impossible for physicians to provide these services to their own patients. To illustrate, OBRA '93 effectively prohibits nephrologists from providing inpatient dialysis services to their own patients at a hospital where they hold a contract to provide the hospital's inpatient dialysis services. The patient is forced to have inpatient dialysis performed by someone other than his or her physician. It is wrong to prohibit physicians from providing inpatient hospital services to their own patients. Clearly over-utilization is not an issue in this case. Receiving dialysis is not an optional therapeutic procedure. Patients with irreversible kidney failure must have regular dialysis to live.

Other subspecialties of internal medicine are experiencing similar problems. For example, oncologists in group practices are effectively prohibited from providing chemotherapy drugs to their cancer patients. Endocrinologists find that they can no longer provide low cost glucose monitors to their diabetic patients. Infectious disease specialists find that they must send patients to home infusion companies for parenteral and enteral nutrition supplies because they are prohibited from providing these items within their practices.

Third, a community-need exception should be created. Many areas, such as inner-city communities and smaller towns, have problems similar to rural areas in attracting nonphysician investors for needed facilities. A discretionary community-need exception would allow physician investment in and referral to outside health care facilities in any locale where the Secretary of Health and Human Services determines that there is both the absence of adequate facilities--a plain medical need--and the absence of alternative financing if physicans are prohibited from investing. This exception is necessary to cover medically underserved areas that do not qualify for the current law rural provider exception.

Conclusion

ASIM appreciates the opportunity to present testimony to the Ways and Means Subcommittee on Health regarding these issues relating to physician self-referral. We believe that the changes we have recommended are essential to ensure that the self-referral law is reasonable, workable and does not disrupt patient access to medically necessary ancillary services.

I'd be pleased to answer any questions from the subcommittee.

Chairman THOMAS. Thank you, Dr. Wilson.
Dr. Tice.

STATEMENT OF ALAN D. TICE, M.D., PRESIDENT, PHYSICIANS FOR QUALITY OUTPATIENT INFUSION THERAPY

Dr. TICE. I am Alan Tice, I am an internist and an infectious disease specialist in Tacoma, Washington, where I have been in practice for 16 years. As part of our practice, we have developed an outpatient IV antibiotic therapy program for the last 14 years.

I am also president of the Outpatient Intravenous Infusion Therapy Association, and the Physicians for Quality Outpatient Infusion Therapy. Both of those organizations were developed and dedicated to developing an interest by physicians in outpatient therapy and to helping payors appreciate the vital role of physicians in outpatient therapy. It is important that you realize that outpatient therapies, particularly outpatient intravenous therapies, are growing rapidly, and for good reason. There are new antibiotics, there is new technology, there is new vascular access and there are new delivery devices to treat the new diseases that we must encounter. It is a rare opportunity with patient intravenous therapy to increase or improve the quality of life, the quality of care, but yet save money and reduce the costs.

At present, approximately 1 in 1,000 Americans receive outpatient intravenous antibiotic therapy each year. In my clinic, I am one of six infectious disease specialists who care for patients with AIDS, with immunosuppressive disorders and serious infections.

As our clinic experience has grown, we now treat more outpatients than inpatients, and we provide intravenous antibiotics to as many outpatients as we do inpatients. I think it is important for you to recognize that two-thirds of our patients are never even hospitalized, even though they have serious infections that warrant intravenous antibiotic therapy.

We treat only our own patients who are referred to us as part of our consultative practice. I can provide intravenous antibiotic therapy for my patients in their home, in the office, or train them in self-administration. We have any device or pump necessary to optimize and individualize therapy.

The legislation on self-referral that came from this Committee has been well-intended, but has had a negative impact on patient care and also limits the doctor's ability to provide the care that is most appropriate for patients. It is possible that the concerns behind the law are relevant to diagnostic testing, but they are not relevant when it comes to patient care.

The problem is that physicians are responsible for the care of patients and are willing to take that responsibility, but are not allowed the freedom and control necessary to provide optimal care to these patients under the self-referral law. Physicians are discouraged from outpatient care not only because of financial limitations, but also because of legal issues, especially those drafted by this Committee.

There are many physicians that I know of who have sold their programs or been reluctant to start programs through their offices because of the concerns over implementation of the self-referral law. The office-based, physician-based model is one of great oppor-

tunity. It is one that integrates and coordinates the services of the nurse, pharmacist and physician, usually under one roof. This makes it a much more efficient unit than others, which are often fragmented. It also puts the physician in control and clearly responsible for the care of people receiving outpatient therapies. It is safer, better and simpler for patients, and it can provide a variety of drugs, technology and adapt continuously to the individual patient needs. I think that this is supported by the Office of Technology Assessment report from a few years ago as well.

For my patients, I can provide virtually all appropriate methods of patient care through the office, unless they are insured by Medicare or Medicaid. Because of the limitations under Medicare and Medicaid, I have the choices only of either keeping them in the hospital, putting them in a nursing home, potentially having them come to the office once a day for therapy if drugs are appropriate in that situation, or referring them to a home care company, over which I have no control in terms of patient care.

My office, I believe, is best suited in that I have a full team of nurses, pharmacists and physicians who are centralized, coordinated. It is far simpler for the patient. We can treat virtually any type of disease, and take advantage of the new technology.

I think it is important that you realize we are treating serious diseases with toxic medications that deserve continued physician input, insight, understanding and change. Not only that, but as people are forced out of the hospital in more complex States of disease, the need for physician input will increase significantly.

An example of this occured a week ago. It involved an AIDS patient that I had who is severely immunosuppressed with multiple diseases, and who is receiving multiple medications, and who also developed a viral infection due to cytomegalovirus in his eyes. He needed intravenous ganciclovir. Because of the limitations of Medicaid, I was unable to provide it for him and he had to be cared for by an outside agency of which I did not have sufficient knowledge, and had no control. I would be in a better position to assist a patient, and a patient would receive better care through use of our own nursing services, through our IV therapy program.

It is to the point where we assign nurses to track patients referred to outside programs so that the ball will not be dropped, the tests will be done, and we can assure the quality of care that we are legally responsible for. I urge you to amend the Stark II law to protect and encourage the physician office model for outpatient infusion therapies, to foster a close doctor-patient relationship, to allow physicians to control the setting in which patients for whom they are responsible receive care, and to take advantage of all the new technologies that are coming in outpatient care.

In my role as a provider and as a representative of the PQOIT organization, we will be happy to help you develop appropriate standards and guidelines for patient care in these settings to avoid abuse. I think that we should be able to dispense drugs, pumps, enteral and parenteral products through our offices for the care of patients treated outside the hospital.

Thank you for this opportunity to come here.

[The prepared statement follows:]

TESTIMONY OF ALAN D. TICE, M.D.
PHYSICIANS FOR QUALITY OUTPATIENT INFUSION THERAPY

Thank you, Mr. Chairman and Members of the Subcommittee, for inviting me to appear before you today to discuss several problems pertaining to the delivery of quality patient care under the new physician self-referral provisions enacted in 1993. I am a physician in the private practice of internal medicine and infectious diseases; the founder and President of the Outpatient Intravenous Infusion Therapy Association (OPIVITA), an organization founded to encourage physicians to provide infusion care for patients outside the hospital and to bring recognition to their important role; and President of Physicians for Quality Outpatient Infusion Therapy (PQOIT), an organization dedicated to a better understanding of the critical role of the physician in outpatient care, and the importance of a close doctor-patient relationship. The physician members of these organizations care for cancer and AIDS patients, and patients with serious bacterial infections.

Introduction

To begin, the physicians who are members of the organizations that I represent recognize and support the need for eliminating financial incentives to overutilize services. We support high Federal standards for the provision of outpatient infusion care. We commend the work of this Subcommittee toward this end. However, we believe that the law, in its current form, has had some unintended effects and that patient care is indeed suffering as a result. The law serves to discourage physicians from becoming involved with outpatient infusion care.

We do not believe that the intention of the self-referral provisions was to prohibit a physician from managing his or her own patients' care. With sicker and sicker patients being discharged from the hospital, now more than ever a physician-based model of delivery of outpatient care should be encouraged. In sum, we believe that the law should be revised to make clear that infusion therapy can remain an integral part of a continuum of care from the physician.

Our specific recommendations include:

- Restructuring the in-office ancillary services exception to clearly allow patients to receive home infusion services from their own physicians, rather than be required to be referred to home infusion agencies.
- Restructuring the in-office ancillary services exception to allow patients to receive enteral and parenteral nutrients in the physician's office, and to allow physicians to dispense the nutrients to their own patients for home use.

Discussion

Basically, the current self-referral law applicable to Medicare and Medicaid patients requires physicians to turn over the care of their own patients to home infusion companies. We believe the current self-referral law must be clarified and amended to allow physicians to care for their own patients.

Under current law, specialists in oncology and infectious diseases are able to provide infusion therapy services to Medicare and Medicaid patients with cancer or AIDS only by requiring these patients to come to the physician's office each and every time that they need infusion therapy, or by caring for them in a hospital. Typically, these physicians already provide infusion services in their offices and have the capability to extend these services as a part of their practice into the patient's home. It is ironic that today's society mourns the passing of the era when doctors made house calls, yet the Federal government has a law that prohibits the doctor's nurse from visiting the patient in the home.

The current law arguably does not permit physicians to dispense from their offices the necessary drugs and nursing services to enable Medicare and Medicaid patients to self-administer this therapy at home. Such home care is safe, if appropriately monitored by a qualified physician. Under the current law, physicians are left with three choices for Medicare and Medicaid patients: (1) either treat the patient in the hospital or a skilled nursing facility; (2) require the patient to receive infusion services in the physician's office every time; or (3) turn the patient's care over to a home infusion agency.

We all would agree that keeping a patient in the hospital, or sending him or her to a skilled nursing home for infusion therapy, is usually not an appropriate, cost effective mechanism for treating Medicare and Medicaid patients. The cost of furnishing home infusion therapy is much less than the costs of treating these patients in hospitals and skilled nursing facilities.

However, with respect to infusion therapy provided to patients in their homes, direct physician management of the care of infusion patients is critical. These patients often are very ill and the drugs involved are toxic. Until the recent advent of advanced technology, these patients would have received this type of treatment in the hospital. Often home infusion companies are not sufficiently staffed to provide home infusion therapy to patients with AIDS, cancer and other diseases requiring complex therapy. In addition, physician management of these patients is necessary, because frequently the drug therapy must be revised. These patients cannot afford to lose contact with their physicians. For example, last year in my office practice, 14 percent of the infusion patients needed their antibiotics changed for a variety of medical reasons.

A physician office provider brings together the full team of physicians, nurses, and pharmacists who all work together for quality patient care. These health care professionals know each other well and can communicate continually in the office. The patients often see the same nurses at home that they see in the office, and appreciate the continuity of care. The physicians appreciate having care provided by nurses that they know and trust. The Office of Technology Assessment, in its 1992 report on the home infusion industry, acknowledged these advantages to a physician office-based home infusion practice.[1]

The current law clearly prohibits physicians from providing enteral and parenteral nutrients -- even in their own offices to their own patients. We believe that requiring physicians to turn their patients over to home infusion agencies for these services is not medically appropriate, in many instances.

In conclusion, I and members of the two organizations that I represent stand ready to work with the Chairman and Members of the Subcommittee to amend the current physician self-referral law so that it does not impede good patient care.

Thank you very much for the opportunity to testify on this important subject. I will be pleased to respond to any questions you may have.

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[1] "Home Drug Infusion Therapy Under Medicare," Office of Technology Assessment (1992).

Chairman THOMAS. Thank you very much, Dr. Tice.
Mr. Kershner.

STATEMENT OF BERNARD A. KERSHNER, PAST PRESIDENT AND MEMBER, BOARD OF DIRECTORS, FEDERATED AMBULATORY SURGERY ASSOCIATION, ALEXANDRIA, VA

Mr. KERSHNER. Mr. Chairman, if I may first congratulate you on your recollection of football trivia. That was indeed Big Daddy Lipscomb that was referred to. My name is Bernard Kershner.

I am president of a company called Sun Surgery Corp., which is based in West Hartford, Connecticut. I am here in the capacity of past president and member of the board of directors of the Federated Ambulatory Surgery Association. FASA is the Nation's leading clinical trade organization of ASCs, ambulatory surgical centers, representing more than 500 member facilities, most of which provide surgical services in a variety of specialty areas and virtually all of which are Medicare certified.

There are over 1,700 Medicare certified surgical centers throughout the country. I thought it might be useful to describe what a surgical center is, and indeed it is a specifically designed health care facility. It provides a clinically appropriate setting for the performance of surgical procedures.

They are similar to hospital outpatient departments in that they provide sterile operating rooms, staff, equipment and surgical supplies and other items and services necessary for a surgeon to perform surgery on an ambulatory or outpatient basis. Virtually all the surgical procedures are performed under controlled anesthesia support, provided by an anesthesia specialist. Physicians' professional services are generally billed separately by the physicians who perform the procedures.

Surgical centers are usually organized as separate legal entities. Most States require surgical centers to meet licensure requirements, including health, safety, staffing and physical plant standards, and indeed many States also require a certificate of need for the establishment of or expansion of a surgical center. Medicare Program also does provide payment to those surgical centers that meet certification standards as set forth by Federal regulation.

I want to comment for a moment on the issue of physician ownership of surgical centers. A substantial number of these facilities throughout the country are owned in whole or in part by the physicians who perform surgical procedures in them. These facilities are used as extensions of physicians' workplaces, have often been established through the use of funds contributed by physicians, and have provided a high-quality, low-cost setting for the performance of outpatient surgical services.

There is no evidence whatsoever that physicians' ownership of ASCs has resulted in increased or unnecessary utilization of surgical services. In fact, the Office of Inspector General has indeed proposed to exclude physician ownership of these facilities from the scope of Medicare and Medicaid antikickback provisions.

During Congress' consideration of both Stark I and Stark II, Congress specifically considered provisions that would have directly or indirectly imposed the physician self-referral provisions on ASCs. After thorough consideration, Congress unequivocally and

deliberately chose to exclude surgical centers from the scope of the self-referral provisions.

Congress did so by limiting the application of those provisions to certain designated health services. That did not include ASC surgical services. Likewise, ASCs generally have not been affected by physician self-referral legislation enacted at the State level.

Unfortunately, the broad interpretation of the Federal selfreferral provisions put forward by certain officials of HCFA, inadvertently impact ASCs, despite clear congressional intent. Let me spend a moment talking about the unintended impact of Stark II, and outline a situation under which surgical centers could be adversely affected for three reasons.

The first, current legislation includes orthotics, prosthetics and prosthetic devices as designated health service. Intraocular lenses, IOLs, which are implanted in conjunction with cataract surgery, are considered a prosthetic device for certain Medicare coverage purposes. And for this reason, some HCFA officials have suggested that the implementation of an IOL in an ASC in connection with cataract surgery may trigger self-referral law.

Likewise, it has been suggested that the implantations of other prosthetic devices, such as ear tubes for patients would likewise trigger the physician self-referral proscriptions. Such a position is clearly without merit.

Let me list the second reason. The inclusion of radiology services as a designated health service may have an inadvertent impact on ASCs as well. A number of HCFA officials have suggested that the term "radiology services" is to be interpreted broadly. Specifically, those officials have suggested that any procedure involving imaging will be considered radiology for the purpose of Stark II.

If this interpretation is adopted, a number of surgical and endoscopic services performed by ASCs could be determined to fall within the scope of Stark II proscriptions.

Finally, the Stark II proscriptions include inpatient and outpatient hospital services as a designated health service. Some freestanding ASCs are located in space either leased from a hospital or might even be on a hospital campus. And freestanding surgical centers provide essentially the same services as hospital outpatient departments.

For these reasons, some attorneys have questioned whether the inclusion of hospital outpatient services as a designated health service also impact ASCs. While FASA does not believe that this position has merit, FASA members have experienced difficulty in obtaining assurances from health care attorneys on this issue.

For these reasons, FASA strongly supports a specific exemption that would make it clear that surgical services performed by Medicare certified ASCs, and designated health services integral to the performance of these surgical procedures, are excluded from the Stark II proscriptions.

We are delighted to have the opportunity to appear before you today and look forward to being able to work with you and provide additional information.

[The prepared statement follows:]

TESTIMONY OF BERNARD A. KERSHNER
FEDERATED AMBULATORY SURGERY ASSOCIATION

My name is Bernard A. Kershner, and I am Past President and a Member of the Board of Directors of the Federated Ambulatory Surgery Association ("FASA"). FASA is the nation's leading organization of ambulatory surgical centers ("ASCs"), representing more than 500 member facilities, most of which provide surgical services in a variety of specialty areas and virtually all of which are Medicare-certified.

Since their inception more than 20 years ago, ASCs have become an increasingly pivotal part of our Nation's health care system. In 1993, over 3,000,000 surgical procedures were performed in ASCs. Moreover, recent analysis suggests that approximately two-thirds of all surgical cases can be performed in this kind of outpatient basis. There are currently over 1,700 Medicare-certified ASCs located throughout the country. The use of ASCs has saved our health care system literally hundreds of millions of dollars relative to the cost of outpatient hospital care and, according to an HHS study, procedures performed in surgical centers cost the Medicare program 30-60% less than these same procedures when performed on an inpatient basis.

I. WHAT ARE ASCs?

It may be useful to describe what ASCs are -- and what ASCs are not. ASCs provide a clinically appropriate setting for the performance of surgical procedures. ASCs -- like hospital outpatient departments -- provide the sterile operating rooms, staff, equipment, and surgical supplies, and other items and services necessary for a surgeon to perform surgery on an outpatient basis. Virtually all the procedures are provided under controlled anesthesia support and are performed by an anesthesia specialist. Physicians' professional services are generally billed separately by the physicians who perform the procedures.

ASCs are usually organized as separate legal entities. Most states require ASCs to meet licensure requirements, including health and safety, staffing, and physical plant standards. And indeed many states also require a certificate of need for the establishment or expansion of an ASC.

The Medicare program does provide payment to those ASCs that meet certification standards set forth by regulation. The Medicare payment methodology used to pay ASCs for the use of the facility (the "facility costs") are based on a prospective payment system. Only procedures on Medicare's "List of Covered Surgical Procedures" are eligible for payment. These procedures are classified into several groups, and a payment rate is established for each group.

II. PHYSICIAN OWNERSHIP OF ASCs.

A substantial number of ASCs throughout the country are owned, in whole or in part, by the physicians who perform surgical procedures in them. These facilities are used as extensions of physicians' workplaces; have often been established through the use of funds contributed by physicians; and have provided a high quality, low cost setting for the performance of outpatient surgical services. There is no evidence whatsoever that physicians' ownership of ASCs has resulted in increased or unnecessary utilization of surgical services; in fact, the Office of the Inspector General has proposed to exclude physician ownership of ASCs from the scope of the Medicare and Medicaid anti-kickback provisions.

During Congress' consideration of Stark I and Stark II, Congress specifically considered provisions that would have directly or indirectly imposed the physician self-referral provisions on ASCs. After thorough consideration, Congress unequivocably and deliberately chose to exclude ASCs from the scope of the self-referral provisions. Congress did so by limiting the application of these provisions to certain "designated health services" that did not include ASC surgical services. Likewise, ASCs generally have not been affected by physician "self-referral legislation enacted at the state level.

Unfortunately, under the broad interpretation of the federal "self-referral" provisions put forward by certain officials of the Health Care Financing Administration ("HCFA"), inadvertently impact ASCs, despite clear Congressional intent.

III. THE UNINTENDED IMPACT OF STARK II.

More particularly, while ASC "facility" services are not listed as a "designated health service," ASCs could be adversely affected for three reasons.

A. The Impact of the Inclusion of "Prosthetic Devices" Under Stark II.

First, the current legislation includes "orthotics, prosthetics, and prosthetic devices" as a "designated health service." Intraocular lenses ("IOLS"), which are implanted in conjunction with cataract surgery, are considered "prosthetic devices" for certain Medicare coverage purposes and, for this reason, some HCFA officials have suggested that the implantation of an IOL in an ASC in connection with cataract surgery may trigger the "self-referral law. Likewise, it has been suggested that the implantation of other prosthetic devices -- such as ear tubes for Medicaid patients would likewise trigger the physician self-referral proscriptions.

Such a position is clearly without merit. IOLS implanted in ASCs are reimbursed at a flat rate of $150 -- a rate that was specifically and deliberately fixed by Congress. This flat payment amount is included in an ASC's "facility" payment for the cataract procedure itself; the IOL is not billed separately. Other prosthetics, orthotics, and prosthetic devices are reimbursed on the basis of a "fee schedule" which does not enable ASCs to profit from the provision of the device involved whatsoever.

Thus, the provision of such prosthetic devices in conjunction with surgical procedures does not in any manner present a potential for abuse.

In addition, an ASC serves as the "workplace" of a surgeon owner, regardless of whether or not the procedure performed by the surgeon involves the implantation of a prosthetic device. For this reason, the "workplace" rationale for the exception of ASCs from Stark II likewise applies to prosthetic devices supplied by ASCs in connection with ASC facility services.

B. The Impact of the Inclusion of "Radiology Services" Under Stark II.

Second, the inclusion of "radiology" services as a "designated health service" may have an inadvertent impact on ASCs. A number of HCFA officials have suggested that the term "radiology" services is to be interpreted broadly, for the purposes of interpreting the physician self-referral provisions. Specifically, these officials have suggested that any procedure that involves imaging will be considered "radiology" for the

purposes of Stark II. If this interpretation is adopted, a number of surgical endoscopic services performed by ASCs could be determined to fall within the scope of the Stark II proscriptions.

C. The Impact of the Inclusion of "Hospital Outpatient" Services Under Stark II.

Finally, the Stark II proscriptions include "inpatient and outpatient hospital services" as a "designated health service." Some freestanding ASCs are located in space leased from a hospital or on a hospital campus, and freestanding ASCs provide essentially the same services as hospital outpatient departments. For these reasons, some attorneys have questioned whether the inclusion of "outpatient hospital services" as a "designated health service" also impacts ASCs. While FASA does not believe that this position has merit, FASA members have experienced difficulty in obtaining assurances from health care attorneys on this issue.

IV. CONCLUSIONS AND RECOMMENDATIONS.

For these reasons, FASA strongly supports a specific exemption that would make it clear that surgical procedures performed by Medicare-certified ASCs -- and "designated health services" integral to the performance of these surgical services -- are excluded from the Stark II restrictions.

One final note is in order: Some have suggested that a specific ASC exception is not necessary if the "group practice" exception is significantly broadened. However, many ASCs -- and virtually all of FASA's members -- are not owned entirely by a single group. Rather, the physician-owners of ASCs often consist of a number of physicians in various medical specialty areas whose practices are not otherwise associated with one another. For this reason, we would respectfully submit that an expansion of the "group practice" exception would not adequately address the problems faced by ASCs with regard to the physician self-referral provisions and that a separate exception is necessary.

FASA is delighted to have the opportunity to submit this testimony and looks forward to working with the Subcommittee to draft an appropriate exception for ASCs. If the Subcommittee has any questions with respect to FASA's position on this most important issue, please do not hesitate to call Gail D. Durant, FASA's Executive Director, at (703) 836-8808.

Chairman THOMAS. Thank you very much, Mr. Kershner.
Mr. Mentz.

STATEMENT OF KEITH MENTZ, PRESIDENT-ELECT, NATIONAL RENAL ADMINISTRATORS ASSOCIATION

Mr. MENTZ. Good afternoon, Mr. Chairman, Members of the Health Subcommittee.

My name is Keith Mentz. I am an area administrator in Philadelphia for National Medical Care, but today I am here appearing on behalf of the NRAA, National Renal Administrators Association, of which I am the president-elect.

The NRAA is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. We represent freestanding and hospital-based facilities which are for-profit and nonprofit providers, located in urban and rural areas.

A number of our members work for physician-owned dialysis units. Our members manage approximately two-thirds of the dialysis units in this country, which provide dialysis services to a majority of Medicare ESRD, end-stage renal disease patients.

We are pleased to have this opportunity to testify before the Subcommittee. My testimony will be brief and focus on the reasons we urge the Subcommittee to, one, eliminate the self-referral ban on physician-owned dialysis facilities contracting with hospitals to provide inpatient acute dialysis services. And two, clarify that the outpatient prescription drug ban does not apply to prescription drugs provided in physician-owned dialysis facilities.

As a result of the self-referral ban on inpatient hospital services included in OBRA 1993, as of January 1, 1995, physician-owned dialysis facilities, group practices and solo practitioners can no longer contract with hospitals to provide the staff and dialysis machines required to dialyze their inpatients if they refer their own patients to the hospital.

The NRAA strongly recommends that the Subcommittee explicitly exempt physicians who have ownership arrangement agreements with hospitals to provide inpatient dialysis services from the self-referral ban for the following reasons. The purpose of the exception is to assure that hospitals will be able to provide acute dialysis services to their patients. Many hospitals cannot afford to provide 24-hour a day acute inpatient dialysis services, and have therefore contracted with local dialysis facilities.

Some of these are practitioners, group practices and physician-owned, and they provide the staff and dialysis machines to dialyze patients with renal failure. Such arrangements result in continuity of care and better quality of care because the same staff is providing the patients with dialysis in both the inpatient and the outpatient setting. The patients also benefit greatly by having their treatments performed by highly qualified staff.

If these hospitals had no other option but to hire their own staff, it is likely that the staff would not be as qualified because they would provide far fewer dialysis treatments than the staff of the physician-owned facility. Smaller community hospitals and hospitals in isolated areas rely upon acute contracts with physician-

owned dialysis facilities in the community to meet patient care needs that cannot be met in any other way.

Without our proposal, some hospitals that cannot afford to staff an inpatient dialysis unit, may have to transfer their critically ill patients with renal failure to other hospitals. This could negatively impact and compromise these patients' health. It might also jeopardize the continuity of physician care, create additional hardships for the patients and their families, and increase the patient's emotional stress.

An example of this is in Clovis, New Mexico, where patients will have to travel 200 miles to another hospital if the hospital in closing is not able to replace its physician-owned acute dialysis contract. We also do not believe that these arrangements should be included simply because we believe that this is an extension of the physician's practice.

Last, because as most inpatient dialysis services are furnished to Medicare ESRD patients, the inpatient dialysis service is covered under the prospective payment system. Under this system, the hospital receives a fixed amount of reimbursement to cover all services furnished to an inpatient, and I believe that studies have shown that hospitalization rates on end-stage renal disease patients have been decreasing over the past couple years.

In summary, our proposed correction will avoid reducing access to inpatient acute dialysis care, help maintain continuity of patient care, allow hospitals to enjoy the most cost-effective means of providing inpatient dialysis services, and not increase costs to Medicare.

The NRAA would also urge you to eliminate the OBRA 1993 ban on outpatient prescription drugs being dispensed in physician-owned dialysis facilities. Nephrologist-owned dialysis facilities, like all other dialysis facilities, order a number of prescription drugs to be given to patients while on dialysis. These medications are covered under Medicare's condition of coverage and are reimbursed by Medicare.

Peritoneal dialysis, which is performed by a patient outside of the dialysis facility, is also categorized as a prescription drug for Medicare reimbursement. Prohibiting physician-owned facilities from prescribing peritoneal dialysis would mean the patients of these physician-owned facilities would be precluded from this form of dialysis.

We do not believe even the authors of the self-referral provision intended to ban the provision of prescription drugs when delivered within the physician-owned dialysis facility. Such a ban would effectively deny patients of these facilities from receiving proper care and could endanger these patients' lives.

We would like to remind you that this Committee agreed with our recommendations last year and included in the Committee's approved health care reform bill legislative language exempting nephrologist-owned dialysis facilities from the self-referral ban when they referred their patients for any dialysis-related services. In fact, this language was also included in the Gephardt bill and the bipartisan Rowland-Bilirakis bill.

We thank you for the opportunity to explain why the self-referral bans when applied to nephrologist owned dialysis facilities make

no sense. They, in fact, are counterproductive and would deny ESRD patients access to the prescription drugs available to all other dialysis patients and potentially subject hospitalized ESRD patients to less-skilled dialysis staff.

The NRAA would like to see last year's Committee language included in any bill this Subcommittee develops to address the problems created by the OBRA 1993 language.

Mr. Chairman, we stand ready to work with the Subcommittee to clarify and improve the OBRA 1993 self-referral law.

Again, thank you.

[The prepared statement follows:]

TESTIMONY OF KEITH MENTZ
NATIONAL RENAL ADMINISTRATORS ASSOCIATION

Good Morning Mr. Chairman and Members of the Health Subcommittee. My name is Keith Mentz, and I am an Area Administrator in Philadelphia for National Medical Care. I am appearing today on behalf of the National Renal Administrators Association of which I am President-Elect.

The National Renal Administrators Association (NRAA) is a voluntary organization representing professional managers of dialysis facilities and centers throughout the United States. We represent free-standing and hospital-based facilities, which are for-profit and non-profit providers located in urban and rural areas. A number of our members work for physician owned dialysis units. Our members manage approximately two-thirds of the dialysis units in this country which provide dialysis services to a majority of Medicare End-Stage Renal Disease (ESRD) patients. The association was founded to provide information and education to our members and to work with the Congress, the Administration, and other oversight organizations on the Medicare ESRD program. Our organization is dedicated to providing quality of care in the most cost effective manner.

We are pleased to have the opportunity to testify before the Subcommittee. My testimony today will focus on the reasons we urge the Subcommittee to: (1) eliminate the self referral ban on physician owned dialysis facilities contracting with hospitals to provide inpatient acute dialysis services and, (2) clarify that the outpatient prescription drug ban does not apply to prescription drugs provided in physician owned dialysis facilities.

EXEMPT PHYSICIAN OWNED DIALYSIS FACILITIES FROM THE INPATIENT HOSPITAL SERVICE BAN

As a result of the self-referral ban on "inpatient hospital services" included in OBRA 1993, as of January 1, 1995, physician owned dialysis facilities, group practices and solo practitioners can no longer contract with hospitals to provide the staff and dialysis machines required to dialyze their inpatients, if they refer their own patients to the hospitals.

The NRAA strongly recommends that the Subcommittee explicitly exempt physicians who have ownership or arrangement agreements with hospitals to provide inpatient dialysis services from the self referral ban for the following reasons.

The purpose of the exemption is to assure that hospitals will be able to provide acute dialysis services to their patients. Many hospitals cannot afford to provide 24 hour a day acute inpatient dialysis services and have therefore contracted with local dialysis facilities (solo practitioners, group practices and physician owned) to provide the staff and dialysis machines to dialyze patients with renal failure. Such arrangements result in continuity of care and better quality of care because the same staff is providing the patients with dialysis care in both the inpatient and outpatient setting. The patients also benefit greatly by having their treatments performed by highly qualified staff. If these hospitals had no other option but to hire their own staff, it is likely that the staff would not be as qualified because they would provide far fewer dialysis treatments than the staff of the physician owned facility.

Smaller community hospitals and hospitals in isolated areas rely upon acute care contracts with physician owned dialysis facilities in the community to meet patient care needs that cannot be met in any other way. Without this proposal some hospitals that cannot afford to staff an inpatient dialysis unit may have to transfer their critically ill patients with renal failure to other hospitals. This could negatively impact and compromise these patients' health. It might also jeopardize the continuity of physician care, create additional hardships for the patients and their families and increase the patients' emotional stress.

Also, we do not believe these arrangements should be included in the self-referral ban because the dialysis services are actually an extension of the physician's practice.

Further, the principal concerns underlying the self-referral prohibition, inflated charges and unnecessary utilization of services, do not apply to inpatient dialysis services. Hospitals already have oversight responsibility for utilization and admission reviews to ensure that patients are not dialyzed inappropriately. Dialysis is not an elective or diagnostic procedure, it is always performed for therapeutic purposes. Once diagnosed, most ESRD patients require dialysis three times a week, for two to four hours per session, for the remainder of their lives. As a result, little opportunity for abuse exists.

Lastly, as most inpatient dialysis services are furnished to Medicare ESRD patients, the inpatient dialysis service is covered under the Prospective Payment System (PPS). Under this system, the hospital receives a fixed amount of reimbursement to cover all services furnished to an inpatient. Therefore, opportunities for increased costs to Medicare for acute dialysis services are virtually non-existent.

In summary, our proposed correction would: (1) avoid reducing access to inpatient dialysis care; (2) help maintain continuity of patient care; (3) allow hospitals to enjoy the most cost-effective means of providing inpatient dialysis services; and (4) will not increase costs to Medicare.

EXEMPT PHYSICIAN OWNED DIALYSIS FACILITIES FROM THE OUTPATIENT PRESCRIPTION DRUG BAN

The NRAA would also urge you to eliminate the OBRA 1993 ban on outpatient prescriptions drugs being dispensed in physician owned dialysis facilities. Nephrologist owned dialysis facilities, like all other dialysis facilities, order a number of prescription drugs to be given to patients while on dialysis. These medications are covered under Medicare's Conditions of Coverage and are reimbursed by Medicare. Peritoneal dialysis, which is performed by a patient outside of the dialysis facility, is also categorized as a prescription drug for Medicare reimbursement. Prohibiting physician owned facilities from prescribing peritoneal dialysis would mean that patients of these physician owned facilities would be precluded from this form of dialysis. We do not believe even the authors of the self referral provision intended to ban the provision of prescription drugs when delivered within the physician owned dialysis facility. Such a ban would effectively deny patients of these facilities from receiving proper care and could endanger these patients' lives.

We would like to remind you that this committee agreed with our recommendations last year and included in the committee's approved health care reform bill legislative language exempting nephrologist owned dialysis facilities from the self referral bans when they referred their patients for **any** dialysis related services. In fact, this language was also included in the Gephardt bill and the Bipartisan Rowland-Bilirakis bill.

CONCLUSION

We thank you for the opportunity to explain why the self referral bans when applied to nephrologist owned dialysis facilities make no sense. They, in fact, are counter productive, and would deny ESRD patients access to the prescriptions drugs available to all other dialysis patients and potentially subject hospitalized ESRD patients to less skilled dialysis staff.

The NRAA would like to see last year's committee language included in any bill this Subcommittee develops to address the problems created by the OBRA 1993 language. Mr. Chairman, we stand ready to work with the Subcommittee to clarify and improve the OBRA 1993 self referral law. Again, thank you.

Chairman THOMAS. Thank you very much, Mr. Mentz.
Dr. Strickland.

STATEMENT OF JAMES STRICKLAND, M.D., PRESIDENT, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

Dr. STRICKLAND. Mr. Chairman, and Members of the Committee, I am James Strickland, president of the American Academy of Orthopedic Surgeons, and a practicing orthopedic surgeon in Indianapolis, Indiana.

On behalf of the 16,000 board-certified fellows of the Academy and myself, I want to thank you for this opportunity to testify before this Committee on the subject of Stark II.

First, let me say that the Academy supports the overall intent of Stark II, namely, to ensure that Medicare patients are protected from fraud and abuse. However, the implementation of the program has activated the law of unintended consequences.

My testimony this morning will address three areas of Stark II that have been problematic for the orthopedic community; namely, shared facilities, issuance of equipment such as splints, canes and crutches, and periodic payments resulting from the sale of a designated health service such as physical therapy.

Mr. Chairman, for the purposes of time, my oral testimony will deal with only the first two issues. With regard to the matter of shared facilities, I am referring to a situation where orthopedic surgeons provide services within a defined and discrete facility, which may contain x ray, physical therapy, a cast application room, and all the necessary nursing and business support.

In this situation, the orthopedists are not formally established as a group practice as defined under Stark II, but rather, have retained their independence through separate billing numbers with insurance carriers. This type of practice arrangement is common.

Sharing the costs of a common facility is done in a number of ways, but the most common is the equal sharing of rent, nursing and business office costs, as well as the cost and revenue of the x ray and physical therapy on a predetermined basis.

Under Stark II, this type of practice arrangement for Medicare patients does not fall under the group practice exemption, but in actuality behaves exactly as a group practice. Consequently, these physicians sharing overhead costs are in violation of Stark II.

I am basing this statement on correspondence the Academy has had with the Health Care Financing Administration officials, and the interpretation of the law by a number of attorneys. The unintended consequence of the law, for example, is that Medicare patients, when presenting themselves for care for a condition which requires a x ray, cannot be x rayed in the discrete suite of rooms used in common by the orthopedists who have decided to share overhead in order to be cost efficient.

Rather, the patient must be sent to some other facility for the x ray and then return to the orthopedist for diagnosis and treatment. If the patient has a broken bone and the orthopedist elects to treat the fracture with closed reduction, that is to say by nonsurgical treatment, the patient must then return again to the other facility for another x ray and once again return to the orthopedist in order to determine that the reduction was indeed successful.

Obviously, this inconvenient and time-consuming shuttle between orthopedic surgeon and x-ray facility is not in the best interest of the patient, nor is it a quality, cost-effective service.

Mr. Chairman, I have made available to the Committee a copy of a letter from a patient that I believe describes the impact and the unintended consequences of this legislation better than I just did. The solution to the inefficient and inefficacious patient care which this shared facility regulation mandates, is, in our opinion, to modify the law to provide an exemption similar to that of the group practice exemption.

This would permit physicians not in a formal group to practice in situations where they work collaboratively within a discrete and definable shared facility, supervising the quality of the work of the shared staff. Moreover, it is recognized that, consistent with the group practice exemption, revenue generated from ancillary services would not be shared on a volume basis. A solution is necessary in order to provide efficient, high-quality, cost-effective and timely care, to our senior citizens.

The next area of confusion under the law seems to be the definition of durable medical equipment. A literal reading of the law has led some lawyers representing our fellows to conclude that applying a splint, putting on a cast, or prescribing and then providing a knee brace, may be considered a referral, and therefore prohibited under the law.

Mr. Chairman and Members of the Committee, these services are the essence of the orthopedic office practice, and an absolutely integral component of our nonsurgical or surgical management of musculoskeletal conditions. I am sure you can imagine the inconvenience to the patient, the potential for professional liability, and the abandonment of the quality of care if patients must be referred to another location not financially connected with the physician providing the initial treatment in order to receive a cast, a splint, a brace, a cane or crutches.

Our solution to that unintended consequence of the law is to provide an exception for the canes, braces, splints, and so forth, are an integral part of the care personally rendered by the physician or by the person under his or her supervision.

Mr. Chairman, it is important here to understand that in an effort to control costs, Medicare has consolidated the reimbursement for DME, durable medical equipment, into four regional carriers. These durable medical regional carriers, are reimbursing DME at a fixed cost. All other charges for orthotics and prosthetic devices are also fixed by Medicare. The only abuse possible on these low-cost items is to charge patients and then not provide the equipment, or to charge and provide these items to every patient.

Mr. Chairman, I can speak for the entire orthopedic community when I say that orthopedic surgeons do not supply prosthetic devices, crutches, casts, splints and canes, to patients whose medical condition does not require them. These items are part of the immediate continuum of care for orthopedic conditions and, for the most part, do not generate profit for the practitioner. Because the Medicare carriers citing the prohibitions of Stark II are in many cases refusing to reimburse for these items, our physicians in the inter-

ests of quality care are supplying items such as crutches or canes to their patients and absorbing the costs.

The decision of orthopedic surgeons to absorb the cost of providing an orthopedic or durable medical equipment is necessitated by the patient's condition. Crutches or a cane is an integral part of the patient's treatment. The decision to withhold the last step of patient care could easily result in a potential lawsuit for failure to provide crutches or a cane should the patient lose their balance and fall while leaving the office.

Mr. Chairman, we support this Committee's continued efforts to provide protections to our senior citizens for unscrupulous individuals, but not the unintended consequences of the Omnibus Budget Reconciliation Act of 1993, because they are neither protecting the patient nor are they encouraging efficient and effective health care.

This concludes my testimony, and I would be happy to answer any questions.

Thank you.

[The prepared statement and attachment follow:]

TESTIMONY OF JAMES STRICKLAND, M.D.
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

Mr. Chairman and members of the Committee, I am James Strickland, M.D., President of the American Academy of Orthopaedic Surgeons and a practicing orthopaedic surgeon in Indianapolis, Indiana.

On behalf of the 16,000 Board Certified fellows of the Academy and myself, I want to thank you for this opportunity to testify before this Committee on the subject of Stark II.

First, let me say that the Academy supports the overall intent of Stark II, namely, to insure that Medicare patients are protected from fraud and abuse. However, the implementation of the program has activated the law of unintended consequences.

My testimony this morning will address at least three areas of Stark II that have been problematic for the orthopaedic community, namely:

* shared facilities;

* issuance of equipment such as splints, canes, and crutches; and

* periodic payments resulting from the sale of a designated health service, such as physical therapy.

SHARED FACILITY

With regard to the matter of shared facilities–I am referring to a situation where orthopaedic surgeons provide services within a defined and discrete facility which may contain x-ray, physical therapy, a cast application room, and all the necessary nursing and business support. In this situation, the orthopaedists are not formally established as a group practice, as defined under Stark II, but rather have retained their independence through separate billing numbers with insurance carriers. This type of practice arrangement is rather common. Sharing of the cost of the common facility is done in a number of ways, but the most common is the equal sharing of rent, nursing and business office cost, as well as the cost and revenue of the x-ray and physical therapy on a predetermined basis.

Under Stark II, this type of practice arrangement for Medicare patients does not fall under the "group practice" exemption, but, in actuality, behaves exactly as a group practice. Consequently, these physicians sharing overhead costs are in violation of "Stark II". I am basing this statement on correspondence the Academy had with the Health Care Financing Administration and the interpretation of the law by a number of attorneys. The unintended consequences of the law, for example, is that Medicare patients, when presenting themselves for care, for a condition which requires an x-ray, cannot be x-rayed in the discrete suite of rooms used in common by the orthopaedists who have decided to share overhead in order to be cost efficient. Rather, the patient must be sent to some other facility for the x-ray and then return to the orthopaedist for diagnosis and treatment. If the patient has a broken bone and the orthopaedist elects to treat that fracture with a closed reduction–that is to say by non-surgical treatment–the patient must then return again to the other facility for another x-ray and once again return to the orthopaedist in order to determine that the reduction was successful. Obviously, this inconvenient and time consuming shuttle between orthopaedic surgeon and x-ray facility is not in the best interest of the patient nor is it a quality/cost-effective service.

Mr. Chairman, at this point I would like to make available to the Committee a copy of a letter from a patient that I believe describes the impact and the unintended consequences of this legislation better than I just did.

The solution to the inefficient and inefficacious patient care which this shared facilities regulation mandates is, in our opinion, to modify the law to provide an exemption similar to the "group practice exemption". This would permit physicians, not in a formal group, to practice in situations where they work collaboratively within a discrete and definable shared facility, supervising the quality of the work of the shared staff. Moreover, it is recognized that, consistent with the group practice exemption, revenue generated from ancillary services would not be shared on a volume basis. A solution is necessary in order to provide efficient, high-quality, cost-effective, and timely care to our senior citizens.

MEDICAL EQUIPMENT

The next area of confusion under the law seems to be the definition of durable medical equipment. A literal reading of the law has led some lawyers representing our fellows to conclude that applying a splint, putting on a cast, or prescribing and then providing a knee brace may be considered a "referral" and therefore, prohibited under the law. Mr. Chairman and members of the Committee, these services are the essence of orthopaedic office practice and an absolutely integral component of our non-surgical or surgical management of musculoskeletal disorders.

I am sure you can imagine the inconvenience to the patient, the potential for professional liability, and the abandonment of the quality of care if patients must be referred to another location not financially connected with the physician providing the initial treatment in order to receive a cast, a splint, a brace, a cane or crutches.

Our solution to this unintended consequence of the law is to provide an exception where the canes, braces, splints, etc., are an integral part of the care personally rendered by the physician or by a person under his or her supervision.

In an effort to control costs, Medicare has consolidated the reimbursement for durable medical equipment (DME) into four regional carriers. These Durable Medical Regional Carriers (DMERCs) are reimbursing DME at a fixed cost. All other charges for orthotics and prosthetic devices are also fixed by Medicare. The only abuse possible on these low cost items is to charge patients and then not provide the equipment, or to charge and provide these items to every patient.

Mr. Chairman, I can speak for the entire orthopaedic community, when I say that orthopaedic surgeons do not supply prosthetic devices, artificial limbs, crutches, casts, splints, and canes to patients whose medical condition does not require them. These items are part of the immediate continuum of care for orthopaedic conditions and, for the most part, do not generate profit for the practitioner.

Although the Medicare carriers citing the prohibitions in "Stark II" are, in many cases, refusing to reimburse for these items, our physicians, in the interest of quality care, are supplying items such as crutches or a cane to their patients and absorbing the cost. The decision of orthopaedic surgeons to absorb the cost of providing an orthotic or durable medical equipment is necessitated by the patient's condition. Crutches or a cane is an integral part of the patient's treatment. The decision to withhold the "last step" of patient care could easily result in a potential lawsuit for failure to provide crutches or a cane, should the patient lose their balance and fall while leaving the office.

PERIODIC PAYMENTS FOR SALE OF A DESIGNATED SERVICE

The final area I wish to speak to is the issue of periodic payment involving the sale of a designated health service listed in Stark II. The problem appears to be with the "isolated transaction rule" in Stark II, which according to a number of attorneys requires a "lump sum" payment for the sale of a service.

One example of the unintended consequence of the law is an orthopaedic group practice which two years ago sold its physical therapy service in anticipation of Stark II. The payments were to be made over a five year period, in equal installments, not related to the volume of patients handled by the facility. In this case the orthopaedic group, knowing the quality of the service provided, refers Medicare patients to this physical therapy service. Although title passed with the sale of the service the arrangement appears to violate the "isolated transaction rule", since the physicians appear to have a "financial interest" in this physical therapy facility until the final installment payment is made.

Our solution to this problem is to permit installment payments, not based on volume or revenues, for the sale of service such as physical therapy. Mr. Chairman, we support this Committee's efforts to provide protections to our senior citizens from unscrupulous individuals but the unintended consequences of the Omnibus Budget Reconciliation Act of 1993 are neither protecting the patient nor are they encouraging efficient and effective health care.

This concludes my testimony and I will be happy to answer any questions.

GEORGE H. MORELLO
1900 Polo Court
San Mateo, California 94402

April 10, 1995

Congressman Fortney Stark
22320 Foothill Blvd., #500
Hayward, CA 94541

RE: ORTHOPEDICS FORBIDDEN TO OFFER XRAY EXAMINATIONS

Dear Congressman:

A few days ago I visited my orthopedic doctor due to excessive pain and my inability to walk more than a few hundred feet. After a thorough examination, my doctor advised that xrays would be required and I fully expected to walk down the hall.

I was told, however, that this is no longer possible due to legislation either authorized or sponsored by you, forbidding xrays to be taken on the same premises.

I was absolutely awestruck and I write you this letter because I want you to know how much inconvenience, pain and suffering you have caused me.

On Friday, April 7, the events were as follows:

1) I arrived at my doctor's office for an 11:00 o'clock appointment and parked in the garage in the basement of his building.

2) At the conclusion of his examination, I was advised to go elsewhere for my xrays which was two blocks away and knowing full well that I wouldn't make it, I decided to drive.

3) Upon arrival at the location of the xray technician, their garage was full and no street parking was available.

4) I then returned to my original starting point, parked the car again and proceeded to walk the two blocks in the rain for my xrays.

5) I then returned to the doctor's office and walked two additional blocks in the rain to get my car and, as a result paid for parking twice.

What possible reason could you have to be motivated to create such hardships, especially for those of us who are getting older? What possesses you to enact a law which has absolutely no benefit to anyone? I have never heard of anything quite so stupid. What business is it of yours to forbid xrays to be taken in a doctor's office if they comply with regulations that ensure the patient's safety?

What's next? Are you going to enact another law to forbid dentists from taking xrays?

If your reasoning is that having xray facilities in-house and that this promotes unnecessary examinations, you, as a legislator should be more concerned about policing the unethical people who perform these acts rather than creating hardships for your constituents.

Now, instead of the doctor being able to read the xrays and make a determination within minutes,I had to go through the above scenario plus wait for the xrays, have them sent to the doctor, return to his office, then have his staff try to fit me into a packed appointment schedule and create more hardships for his staff and the other patients who are waiting.

Honestly, Congressman, don't you have anything else to do? I could name a hundred projects which need attention from influential people like you. If you can get a law passed so easily as this one was, why aren't you out there doing something constructive like ending the subsidies to the tobacco farmers or the closing of the helium plant which we haven't had use for since 1943. There are dozens of these worthwhile projects that need a champion like you. Try devoting your time to something more meaningful instead of creating headaches for us who simply don't need them.

Wake up and smell the roses. Your legislation is out of step with reality. You have not helped anyone but rather have created a nightmare.

Yours truly,

George H. Morello
GHM/ms

Chairman THOMAS. Thank you, Dr. Strickland.

No direction to my comment, but from a content analysis of statements, you used the phrase "unintended consequences" about as many times as Mr. Grob used "draw your own conclusions." And if you will allow me, I will draw my own conclusions about the unintended consequence.

Mr. Stark.

Mr. STARK. Thank you, Mr. Chairman.

Just a couple of comments and reassurances.

Dr. Wilson, your comments are timely and were timely a couple of years ago. In the 1994 Health Reform Act, we got into some of the fine print, there was a paragraph or two which basically solved your problem.

I would submit, I discussed this with the Chairman. This is one of the things that should have been corrected and I wish we had done it sooner, but there are some things in that bill we could probably peel out, this section being somewhat less controversial.

I would say the same thing to Dr. Strickland. Far be it for any Member of this Subcommittee to take canes and crutches away from disabled folks. You do have a problem in your group, Doctor, with the physical therapists. Their complaint is that if you control the physical therapy center, then they as private practitioners do not have a chance to get the business.

That is a turf battle that may or may not cost more or may or may not provide better care, but it is a turf battle. You have got to understand that we represent both orthopedic surgeons and physical therapists, and if there was some way that we could find a way for you guys to make peace, I think that would help a lot.

But basically, your company operates 500 or more dialysis centers around the country. And Mr. Burger agrees that there is a real potential for abuse by nephrologists in referring to in-hospital dialysis equipment which they own. I will not bore you with all the details of your boss' letter, but there are many instances where this is just too great an opportunity.

We deal with a $16 fee for dialysis in a center, for the physician supervising it, as opposed to $180 fee for the physician supervising that dialysis in a hospital. That is not your issue, but there are some incentives for payment that are probably our fault for setting the payments. I think that this is something that I—we ought to look at in the dialysis area.

It is the one area in the country, in the world, that we pay for everything, basically, and to everybody it is, in fact, government health care. I think we have to be very careful.

I would like to enter that in the record and say that is an area which we should still view with some concern. The other issues of where the law has had unintended consequences or has created problems for you to carry on your practices efficiently, I agree should be corrected. Some we have already tried, and I appreciate your bringing others to our attention. I am sure that the Chairman will be glad to help if we can correct those inequities.

Thank you, Mr. Chairman.

Mr. MENTZ. Mr. Stark, can I clarify one thing?

I do work for National Medical Care. I have for the last 4 weeks. I was an administrator for the past 10 years of a physician-owned

dialysis facility. I cannot say that the main reason the physician sold the facility was because of the Stark legislation, but it did have an impact. So I just want to note that Dr. Burger and myself disagree.

Mr. STARK. Did he make a good profit when he sold it?

Mr. MENTZ. I cannot tell you. But nevertheless, I just—when I am here, as you are, representing your constituents, I am here representing the membership of the National Renal Administrators Association.

Thank you.

Chairman THOMAS. Dr. Tice, I am looking—go ahead, someone wants to respond.

Dr. WILSON. Mr. Chairman, I wanted to respond to Congressman Stark's remarks in regard to the shared lab, and I was aware of that previous effort for which we are very grateful. I am also very grateful for your assurances today, I appreciate it very much.

Chairman THOMAS. However, there is still no package under the tree. And, I did not hear Dr. Tice's name mentioned as being on the present list.

I can assure you that as far as I am concerned, what happened to you was an overzealous intent to create consequences on the part of the previous Majority on another Committee. And, that I am very pleased to hear my colleague and Ranking Member indicate that there is an opportunity to go in to make some specific corrections. I think he will probably fall by the wayside before I do in making changes in this area, but I would be pleased to have him with me as far as he feels comfortable in going, in correcting what I happen to think are some relatively egregious and overreaching provisions.

None of us, including those medical doctors who have taken oaths, want someone to profit unnecessarily and unfairly. I think this law can be adjusted in a number of ways without disturbing that fundamental agreed-upon goal.

I want to thank all of you.

Dr. Wilson, I am hopeful that the correction that apparently was in most of the bipartisan Republican and Democrat packages gets by the counting post soon, and it is accompanied by a number of other changes that will take care of most of the very real, very practical concerns that you have pointed out.

I very much appreciate your testimony, and your willingness to be here to help us focus on the absurdities of this law.

Thank you very much.

Chairman THOMAS. And now, we welcome the last panel, Dr. Templeton, Mr. Connolly and Dr. Mitchell.

Thank you all very much.

As I indicated to earlier panels, if you have written statements, they will be made a part of the record without objection.

Beginning with Dr. Templeton and then moving across the panel, you may proceed to inform us in any way you see fit.

Dr. Templeton.

STATEMENT OF EMMETT O. TEMPLETON, M.D., CHAIRMAN, BOARD OF CHANCELLORS, AMERICAN COLLEGE OF RADIOLOGY

Dr. TEMPLETON. Thank you very much.

Thank you, Mr. Chairman, for inviting the American College of Radiology to present the following statement from the physician self-referral prohibitions as passed in OBRA 1989 and 1993.

My name is Neal (Emmett) Templeton. I am a physician in private practice in Birmingham, Alabama.

I appear before the Committee today as chairman of the board of chancellors for the American College of Radiology.

The college represents 30,000 physicians and physicist members who provide diagnostic and therapeutic services to patients. Since 1985, the college has had official policy that physicians should not have a direct or indirect financial interest in diagnostic or radiation oncology facilities to which they refer patients. And we support the current statutes which strive to eliminate this conflict of interest by prohibiting such ownership arrangements in health care.

This position is shared by numerous physician and health care organizations. The ACR has long held that self-referral arrangements lead to inappropriate utilization of medical services, and the justification for development of these arrangements is largely contrived.

Having laid out our ethical policy, I would like to remind the Subcommittee that it was not the position we began with some decade and a half ago. Instead, we have learned through experience that joint ventures, which include referring physicians, did not proliferate because of a need to increase access to care, or to achieve economic economies of scale in providing health care services. Rather, we believe these arrangements are chiefly intended to capture the market for a given set of health care services, and that this control does not benefit patients. In radiology, a series of studies published over the last 5 years have reaffirmed the need for these prohibitions.

While we support efforts to provide high-quality patient care through more cost-effective delivery mechanisms, we must urge your caution in proposing any modification in the laws which would create loopholes for referring physicians' financial involvement in health facilities. If joint ventures are allowed to simply declare themselves shared facilities or offices without walls, then the intent of the law will be circumvented.

Fraud and abuse problems with increased utilization will be simply changed from physician-owned facilities to physicians' offices. Unfortunately, there will always be those who will want to create elaborate kickback schemes and abusive referral arrangements to augment their income, as Congress seeks to restrict the growth of the Federal health care programs and the market restricts income from private sources. But the passage of these laws has already had a substantial impact in reducing overutilization of radiologic and other designated health service, thus saving taxpayers as well as private sector dollars.

CBO scored specific budget savings for the self-referral laws of $350 million over 5 years. These savings should be carefully considered in the context of any changes proposed. The self-referral ban

in Medicare and Medicaid has also had an indirect effect of eliminating similar corresponding cost in the private sectors.

Dr. TEMPLETON. In short, we believe that alternate methods for controlling of fraudulent and abusive referrals has cost the U.S. health care system and the Federal Government more money.

Mr. Chairman, I would like to make one critical point. The claims that these laws have impeded the development of managed care are plainly unfounded. In States like California and Florida, which have self-referral bans on all payers, managed care growth has been unchanged by the self-referral prohibitions.

In conclusion, we believe that access to quality radiology services has not been restricted in any way by the self-referral laws. 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 legitimate managed care arrangements. However, we believe strongly that exploitive and unethical practices should not be condoned under the guise of competition. These arrangements ultimately hamper rather than encourage competition and should not be allowed.

Thank you.

[The prepared statement follows:]

Testimony of the American College of Radiology
to
The Subcommittee on Health
House Ways and Means Committee
by
Emmett O. Templeton, M.D.
May 3, 1995

The American College of Radiology is pleased to present the following statement on the physician self-referral prohibitions in the Social Security Act as passed under the Omnibus Budget Reconciliation Acts of 1989 and 1993 (OBRA 1989 and 1993). The ACR represents 30,000 physician and physicist members who provide diagnostic and therapeutic services to patients.

Since 1985, we have advocated the ethical principle that physicians should not have a direct or indirect financial interest in diagnostic or radiation oncology facilities to which they refer patients; and we support legislation which 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.

The ACR has long held that these financial arrangements lead to inappropriate utilization of medical services and that the justification for development of these arrangements is largely contrived. Having stated our policy position, I would like to remind the subcommittee that it was not the position we began with some decade and a half ago. Instead, we have learned through experience that joint ventures which include referring physicians did not proliferate because of a need to increase access to care or to achieve economies of scale in providing health care services.

Rather, we believe these arrangements are chiefly intended to capture the market for a given set of health care services and that this control does not benefit patients. A series of studies – published over the last five years – have reaffirmed the need for these prohibitions. 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. We believe these investigations clearly show that this type of market control has led to increased utilization, higher prices and lower quality which generate unmandated large profits.

We are also concerned about the resultant exploitation of referral-dependent physicians as referring physicians band together to exercise market control and by subterfuge, demand a portion of the practice income of the consulting physicians in return for referrals. The practice of physicians seeking compensation for this market control of patient referrals is pervasive and we believe any doubt as to the impropriety of these actions, ethically, legally or morally, should be eliminated.

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 structured 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 actual abuse and exploitation of patients by unethical practices, and the flagrant disregard of physicians' ethical responsibilities to the patient to be so great and so pervasive that these arrangements could not be ignored and 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 to be "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 self-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.

Access to Care

Those who support the continuation of financial arrangements among physicians or the weakening of the physician self-referral laws have argued that these ventures are necessary to assure access to services in underserved areas. We doubt that the predominate reason for joint ventures is to provide access to services in rural or underserved areas. A major conclusion in the 1991 Florida study was that "joint ventures do not increase access to rural or underserved indigent patients." We believe that other studies underway will further support this finding.

A second point to be made in regard to access is specifically addressed to the argument that health services would be unavailable without using referring physicians as a source of capital for these facilities. We do not believe this is the case. Most often, referring physicians' participation in these joint ventures involves only signing a note for debt, not in providing capital for the facility. If in fact, an area in the country finds that lack of capital is restricting access to services, a clear exception has be made when there is concrete evidence that the referring physicians involved in a rural setting are actually providing the needed

capital for the facility. We do not believe that these joint ventures are created because "there's no money in town."

Cost Savings

While we support efforts to provide high quality patient care through the more cost-effective delivery mechanisms, we must urge your 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 physicians' 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.

As example, you may recall that the Congressional Budget Office (CBO) has been able to score these specific savings as a result of these laws as they affect both Medicare and Medicaid. These savings should be recognized and carefully considered in the context of any changes proposed. The self-referral ban in Medicare and Medicaid has also had an indirect affect 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 system 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 legitimate 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.

Chairman THOMAS. Thank you very much, Dr. Templeton. It is my understanding that Mr. Connolly is ill and substituting on behalf of the American Physical Therapy Association is Mr. Weinper. Is that correct?

STATEMENT OF MICHAEL WEINPER; ON BEHALF OF JEROME B. CONNOLLY, SENIOR VICE PRESIDENT FOR HEALTH POLICY AND PRACTICE, AMERICAN PHYSICAL THERAPY ASSOCIATION, ALEXANDRIA, VA

Mr. WEINPER. Yes, that is, thank you. Chairman Thomas and Members of the Subcommittee, I am Michael Weinper, and as you pointed out, I am here speaking on behalf of the American Physical Therapy Association in place of Jerry Connolly, the APTA senior vice president for health policy and practice, who is, unfortunately, ill today.

I am a physical therapist with 25 years of experience, and I practice in southern California both clinically and as the chief executive officer of a managed health care organization for a physical therapist called Physical Therapy Provider Network. The APTA is the national association representing more than 66,000 physical therapists, physical therapist assistants and students of physical therapy.

The APTA shares the desire of the American public, political leaders, and other health care providers to make quality health care services more accessible and affordable for all Americans. Two 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.

Today, I appear before you to encourage this Subcommittee not to retreat from this important public policy, and ask that you would encourage its implementation and strong enforcement. At the same time, APTA is sympathetic to the concerns of the physician community given the fact that the administrator of HCFA has not yet developed any regulations to aid the physicians in their attempts to comply with the law.

The APTA recommends that this Subcommittee encourage the HCFA administrator to promulgate and implement the necessary regulations to make it easy for physicians to ensure their compliance. 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 the William Mercer Corp., an independent consulting firm.

This study found that if an injured worker received initial treatment from a physician with an ownership interest in physical therapy services, the patient received a referral to physical therapy 66 percent of the time. If, however, 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 percent or less than half of that of the owner frequency.

In light of such findings, patients are left with much cause for concern. Was the referral based on 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 the physical therapy generated approximately $233 million per year in services delivered for economic rather than clinical reasons. These are costs neither our National health care system nor especially our Nation's elderly should ever have to bear.

With regard to consumer choice, we put into the record some examples where patients' freedom to choose their physical therapist was denied by physicians with financial interest in physical therapy and facilities. With the emerging free market in health care reform evolving more than ever, it is increasingly imperative that consumers be allowed to exercise their freedom of choice when convenience, quality, and economics hang in the balance.

Another study demonstrates that physician self-referral drives up utilization 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 serving in two settings, freestanding physical therapy facilities and comprehensive rehabilitation centers that provide physical therapy services.

The findings were dramatic. The joint ventures that our physician-owned physical therapy facilities provided 43 percent more visits per patients than did nonjoint venture or, in other words, nonphysician-owned physical therapy facilities did. Consequently, the physician-owned joint ventures generated approximately 31 percent more revenue per patient than in a nonjoint venture facility.

At comprehensive rehabilitation facilities, 35 percent more physical therapy visits were provided per patient in joint venture facilities than in nonjoint venture facilities. More importantly, the Florida study found that the 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. An example from southern California can serve as a meaningful illustration of why particularly in the free market health care reform this current law is reasonable and necessary. A physical therapy provider network was engaged with insuring a pilot project to demonstrate the effects of self-referral on the cost of care.

A physician impacted by this study contacted his local independent physical therapist and threatened to withhold all of his referrals if the physical therapist participated in the study or remained with the managed care network. Moreover, physicians then made contact with his colleagues in an attempt to have them boycott any private practice physical therapy practice associated with the managed care network. If free market reform is going to succeed, this kind of behavior on the part of providers motivated by more economic desire than medical necessity must have some restraint resulting in the reasonable balance.

I would like to comment briefly on the proposed amendments to the current statute. First, direct physician supervision. APTA

opposes provisions that would amend the physician supervision requirement of nonphysician 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 nonphysician practitioners under the physician's employment. Regarding the removal of physical therapy from the designated health care services list, APTA again is opposed to proposals to eliminate physical therapy from the list of designated services under the current statute.

As we have shown here today, numerous studies indicate the relationship between physicians and referrals to physical therapy services in which they have a financial interest leads to a significantly higher cost to the payer. To remove physical therapy from the list of regulated services would allow this overutilization to go unchecked, costing the American people and the Medicare Program many millions of dollars.

Next, investment in rehabilitation facilities. The 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 CORFs, comprehensive outpatient rehabilitation facilities.

On reporting requirements, APTA strongly opposes proposals to eliminate reporting requirements under the current State statute. These requirements provide information necessary to effectively enforce the law and must be maintained. It is vital that the Secretary of Health and Human Services have the necessary information gained from these requirements to ensure the Medicare system is used responsibly.

Regarding preemption of State laws, the APTA firmly opposes the preemption of State laws governing physician ownership and referral. The legislatures of at least 30 States have found this problem troubling enough that they have found it necessary to act. 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, as well as Maryland have laws requiring the provider to disclose his financial interest in the facilities where his patients are referred. Federal preemption of these State laws interferes with the State's ability to enact cost-saving legislation critical to their budget processes.

In conclusion, it is difficult to comprehend why Congress, facing a budget deficit and a Medicare solvency problem, would choose to repeal a law which alone can save the Medicare Program $350 million by the end of the decade.

In summary, APTA is supportive of the current prohibition and encourages the Subcommittee to urge the administration to actively implement and enforce the law. APTA stands ready to assist the Subcommittee in any possible way. Thank you, Mr. Chairman, for the opportunity to present these views.

[The prepared statement follows:]

Statement

of the

American Physical Therapy Association

before the

House Ways and Means Committee
Subcommittee on Health

concerning

Physician Ownership and Referral

May 3, 1995

Chairman Thomas, and members of the Subcommittee, I am Jerome Connolly, PT, Senior Vice President for Health Policy and Practice for the American Physical Therapy Association (APTA). Twenty-two years ago I graduated from the Mayo Clinic School of Physical Therapy. Before joining APTA early this year as Senior Vice President of Health Policy and Practice, I spent 19 of my 22 years as a physical therapist in private practice, many of those years serving rural areas in Montana. I am delighted to be here today, and to have an opportunity to represent APTA's views and some of my personal and professional experience with this issue of physician self-referral particularly as it affects the delivery of physical therapy to Medicare and Medicaid beneficiaries.

The APTA is the national association representing more than 66,000 physical therapists, physical therapist assistants, and students of physical therapy. The 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.

Two 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. Today, I appear before you to encourage this Subcommittee not to retreat from this important public policy,

and to ask you to encourage its implementation and strong enforcement.

At the same time, APTA is sympathetic to the concerns of the physician community given the fact that the Administrator of the Health Care Financing Administration (HCFA) has not yet developed any regulations to aid the physicians in their attempts to comply with this law. The APTA recommends that this Subcommittee encourage the HCFA Administrator to promulgate and implement the necessary regulations to make it easy for physicians to ensure their compliance.

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 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 are left with much cause for concern. Was the referral based on 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 especially our nation's elderly should not have to bear.

Consumer Choice

Were the patients given the freedom to choose their physical therapist? Or were they simply referred to the physical therapy services in which their physician invested as in these couple of examples:

From **Indiana** where an orthopedist instructed a patient to go to his Physician-Owned Physical Therapy service rather than to a clinic which was conveniently located in the patient's own community. Even after repeated pleas the physician firmly indicated he would not continue to serve as the treating physician if the patient insisted otherwise.

From **Montana**: An elderly woman with a back condition was given a referral for physical therapy as long as she would take it to the physical therapy service in which the physician had a financial interest. In spite of the fact that her nephew had a private practice in the same town with a solid reputation in both cost and quality, the physician refused to allow Edith to choice to receive her physical therapy where she preferred.

In these two instances, now with the emerging free market health reform evolving more than ever, it is increasingly imperative that consumers be allowed to exercise their freedom of choice when convenience, quality and economics hang in the balance.

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 non-joint-venture (or non-physician owned) physical therapy facilities. Consequently, the physician-owned joint-ventures generated approximately **31%** more revenue per

patient than in non-joint-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 non-joint-venture facilities, and that joint-venture facilities did not increase access to services. In fact, the **non-joint-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.

An example from Southern California can serve as a meaningful illustration of why particularly in free market health reform, this current law is reasonable and necessary. A physical therapy provider network comprised of all small businesses (private practices) was engaged with an insurer in a pilot project to demonstrate the effects of self-referral of claim payment. In the very early going of the project a physician contacted not only his local independent private physical therapist and threatened to withhold all of his referrals if the PT participated in the study or remained with the managed care network. Moreover, the physician then made contact with his colleagues in an attempt to have them boycott any private physical therapy practice associated with the managed care network. If free market reform is going to succeed, this kind of behavior on the part of providers motivated more by economic desire than medical necessity must have some restraint

resulting in reasonable balance.

Even with the preponderance of empirical data pointing toward the negative effect of physician self-referral, some in the health care community would like to see this Subcommittee overturn the law even before its implementation. I would like to take this opportunity to comment briefly on proposed amendments to the current statute.

Direct Physician Supervision

APTA opposes provisions that would 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 or 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 proposals to 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 a significantly higher cost to the payer. To remove physical therapy from the list of regulated services would allow this overutilization to go unchecked, costing the American people and the Medicare program many millions of dollars.

Investment in Rehabilitation Facilities

The 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 Rehabilitation 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. We do not wish to limit physician's investment opportunities; we only want to ensure that physicians do not misuse their referral powers to such facilities in order to turn a profit. Additionally, APTA feels exemptions provided in the law are reasonable and provide adequate flexibility for a physician to address the medical needs of his or her patients.

Reporting Requirements

APTA strongly **opposes** proposals to eliminate reporting requirements under the current statute. These requirements provide information necessary to effectively enforce the law and must be maintained. It is vital that the Secretary of Health and Human Services have the necessary information gained from these requirements to insure the Medicare system is used responsibly. These requirements are reasonable particularly in view of the objective data studies have demonstrated. To eliminate this portion 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 found it necessary to act. 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, as well as 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. And, Texas and Rhode Island enacted a basic anti-kickback laws stating 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.

Conclusion

It is difficult to comprehend why Congress, facing a budget deficit and a Medicare solvency problem, would choose to repeal a law which alone can save the Medicare program **$350 million** in physical therapy payments alone by the end of the decade. When imaging services, clinical laboratory tests and physical therapy are combined and the law is strengthened and expanded, the total savings is likely to reach into the billions. Real dollars, real savings and real sound decision-making. In summary, APTA is supportive of the current prohibition and encourages the Subcommittee to urge the Administration to actively implement and enforce the law. APTA stands ready to assist the Subcommittee in any way.

Thank you, Mr. Chairman for the opportunity to present these views.

Chairman THOMAS. Thank you, Mr. Weinper.
Dr. Mitchell.

STATEMENT OF JEAN M. MITCHELL, PH.D., ECONOMIST, GEORGETOWN UNIVERSITY

Ms. MITCHELL. Mr. Chairman and members of the Health Subcommittee, my name is Dr. Jean Mitchell. I am a Ph.D. economist, and I am currently an associate professor in the graduate public policy program at Georgetown University.

Prior to joining the faculty at Georgetown, I was an associate professor at the department of economics at Florida State University. While on the faculty at FSU, I was the principal investigator of the Florida study on physician joint venture arrangements, which was mandated by the Florida legislature.

I am pleased to be here today to discuss the effects of physician self-referral arrangements on the utilization and costs of health care services, and the implications of the current legislation which prohibits these abusive ownership arrangements. I think it is important to clarify that there are two types of physician self-referral arrangements.

The first is within office self-referral, which occurs when a physician orders a test or a diagnostic procedure for a patient that is performed in the physician's office. Examples include an orthopedic surgeon who orders a series of x rays for a patient which are performed using equipment situated in his or her office.

The second type of physician self-referral arrangements are known as physician joint ventures. Under these arrangements physicians have ownership interests in health care facilities and businesses to which they refer patients for services, but at which they do not practice.

The current Federal law pertains only to physician joint ventures. All within office physician self-referral arrangements are legal and thus are not subject to any prohibition on referrals. The current Federal law was enacted subsequent to the publication of several empirical studies, which documented the consequences of physician joint venture arrangements.

These studies include the following: Mitchell and Scott, which was published in JAMA July 1992, it highlights the prevalence and scope of physician joint ventures in Florida; Mitchell and Scott published in Yale Journal on Regulation, summer 1992, which highlights the complexity of these ownership arrangements and how multiple levels of incorporation or partnership can make it very difficult to identify the owners of the parent organization; Mitchell and Scott published in JAMA, October 1992, which documented the increased costs, higher utilization, limited access to poor persons, and lower quality of services that characterized physician-owned physical therapy and rehabilitation facilities in Florida.

Mitchell and Sunshine, published in New England Journal of Medicine, November 1992, which examined physician joint ventures in radiation therapy. We found that such arrangements decreased access to poor persons, had greater utilization and higher costs. Also limited indicators suggested the quality is lower in radiation therapy joint ventures. Swedlow and colleagues, published in New England Journal November 1992, examined workers' com-

pensation data from California and found physician self-referral resulted in significantly greater use of physical therapy services, higher costs for psychiatric services, and a higher percentage of MRI scans deemed to be inappropriate.

Mitchell and Scott, published in Medical Care February 1994, found that clinical labs owned by referring physicians had higher utilization and costs than those not owned by physicians; Mitchell and Sass, forthcoming in the Journal of Health Economics, examined Florida physical therapy data and found that after controlling for other confounding factors, including case mix, that patients treated at physician-owned clinics received on average 50 percent more visits than those treated at independent facilities.

Three other published studies have documented the increased utilization and higher costs that accompany within-office physician self-referral arrangements. These include Childs and Hunter, published in Medical Care, 1992; Hillman and colleagues, New England Journal of Medicine, December 1990; and Hillman and colleagues, published in JAMA October 1992.

Several other studies by the Federal Government have also documented the negative consequences of physician joint ventures. These include the 1989 OIG study, which was the basis for the initial prohibition on physician self-referral to clinical laboratories, the 1989 GAO study looking at ownership of clinical labs and imaging facilities in Pennsylvania and California, and the 1993 GAO followup analysis of the Florida joint venture study by Mitchell and Scott.

This comprehensive review of the empirical evidence on physician self-referral indicates that these ownership arrangements have a negative effect on utilization, costs, access, and quality. Specifically, the general consensus of all the available evidence is that the financial incentives that accompany physician self-referral arrangements result in increased utilization of services and higher costs to patients.

Moreover, physician joint venture facilities appeared to cream skim the patients with good insurance and thus treat relatively few indigent and underinsured patients. As regards geographic access, all physician joint ventures in Florida were located in metropolitan areas. Hence, these do not, as claimed by proponents, increase access to services, and new technology to persons residing in medically underserved or rural areas.

Finally, there is some limited evidence suggesting that joint ventures have adverse effects on quality. None of the evidence to date has been able to evaluate whether the increased utilization that accompanies the practice of physician self-referral represents inappropriate or unwarranted services.

Yet, there is no evidence to date demonstrating that physician self-referral arrangements have any benefits to consumers.

The current law is based on extensive published empirical research documenting the negative consequences of physician joint ventures. Congress should be commended for enacting comprehensive legislation on the basis of good empirical research that has been published in the leading medical journals and thus approved by the medical community.

Most researchers and policymakers recognize that the current law has a number of loopholes that limit its potential effectiveness. For example, because within office self-referral arrangements are still legal, physicians can skirt the prohibition on referrals to free-standing facilities by putting diagnostic equipment or physical therapy in their offices.

In fact, the current law has fostered the growth of clinics without walls. Also, the Federal law does not apply to privately insured patients nor does it encompass all types of medical services. The current law should be reformed to eliminate such loopholes. The reforms suggested by those opposed to the current laws will essentially make the current prohibition worthless.

The reporting requirements of the current law are critical for enforcement and monitoring these abusive ownership arrangements. The claims by opponents that the current law is burdensome to physicians is based on anecdotal evidence. I can tell you from my own experience collecting the data on all the physician owners in Florida, this was not a very difficult task. You simply give them the form, have them fill it out, and tell them there is a fine if they do not give you the information. It is a great way to collect money, especially given that Medicare is having so many problems.

Moreover, there is no empirical evidence that exists to support the contention that managed care will eliminate the increased utilization and the higher costs linked to physician self-referral. Given that less than 10 percent of Medicare patients are currently enrolled in HMOs, it is highly unlikely managed care plans will be capable of resolving this problem.

In conclusion, any reforms that weaken the current law would result in increased utilization and higher costs to consumers. Thank you for providing me with the opportunity to testify before you here today.

[The prepared statement and attachment follow:]

STATEMENT OF JEAN M. MITCHELL, PH.D.
ASSOCIATE PROFESSOR,
GRADUATE PUBLIC POLICY PROGRAM, GEORGETOWN UNIVERSITY

Mr. Chairman and Members of the Health Subcommittee, Committee on Ways and Means

My name is Dr. Jean M. Mitchell. I hold a doctorate in economics from Vanderbilt University and I am currently an associate professor in the Graduate Public Policy Program at Georgetown University. Prior to joining the faculty at Georgetown, I was an associate professor in the Department of Economics at Florida State University. While on the faculty at FSU, I was the principal investigator of the Florida study on physician joint venture arrangements, which was mandated by the Florida legislature. I am pleased to be here today to discuss the effects of physician self-referral arrangements on the utilization and costs of health care services, and the implications of the current legislation which prohibits these abusive ownership arrangements.

There are two types of physician self-referral arrangements. Within-office self-referral occurs when a physician orders a test or diagnostic procedure for a patient that is performed in the physician's office. Examples include an orthopedic surgeon who orders a series of x-rays for a patient which are performed using equipment situated in his/her office. The second type of physician self-referral arrangement are known as "physician joint ventures". Under these arrangements, physicians have ownership interests in health care facilities and businesses to which they refer patients for services but at which they do not practice. The current federal law pertains only to physician joint ventures; all within office physician self-referral arrangements are legal and thus are not subject to any prohibitions on referrals.

The current federal law was enacted subsequent to the

publication of several empirical studies which documented the consequences of physician joint venture arrangements. These studies include the following: 1) Mitchell and Scott (JAMA, July 1992) highlight the prevalence and scope of physician joint ventures. 2) Mitchell and Scott (Yale Journal on Regulation ,Summer 1992) highlight the complexity of these ownership arrangements. Multiple levels of incorporation or partnership can make it difficult to identify the owners of the parent organization. 3) Mitchell and Scott (JAMA, October 1992) documented the increased utilization, higher costs to consumers, limited access to poor persons, and lower quality of services that characterize physician-owned physical therapy and rehabilitation facilities in Florida. 4) Mitchell and Sunshine (New England Journal of Medicine, November 1992) examined physician joint ventures in radiation therapy. They found that such arrangements decreased access to poor persons, had greater utilization and higher costs. Also, limited indicators suggest that quality is lower in joint ventures. 5) Swedlow and colleagues (New England Journal, November 1992) examined workers compensation data from California and found physician self-referral resulted in significantly greater use of physical therapy services, higher costs for psychiatric services, and a higher percentage of MRI scans deemed to be medically inappropriate. 6) Mitchell and Scott (Medical Care, February 1994) found that clinical labs owned by referring physicians had higher utilization and costs than those not owned by physicians. 7) Mitchell and Sass (Journal of Health Economics, forthcoming) examined the Florida physical therapy data and found that after controlling for other confounding factors,

patients treated at physician-owned clinics received on average 50% more visits than those treated at independent facilities.

Three other published studies have documented the increased utilization and higher costs that accompany within office physician self-referral arrangements. These include Childs and Hunter (Medical Care, 1972); Hillman and colleagues (New England Journal of Medicine, December 1990) and Hillman and colleagues (JAMA, October 1992).

Several other studies by the federal government have also documented the negative consequences of physician joint ventures. These include: 1) the 1989 OIG study which was the basis for initial prohibition on physician referrals of Medicare patients to clinical labs in which the referring physician had an investment interest; 2) the 1989 GAO study which documented physician ownership of clinical labs and imaging facilities in Pennsylvania and Maryland; 3) the 1993 GAO followup analysis of the Florida joint venture study by Mitchell and Scott (1991). Their analysis of 1.3 million claims for Florida Medicare referrals for imaging services revealed that physician owners of imaging facilities had significantly higher referral rates for all types of imaging services in comparison to nonowners. The differences were greatest for costly, high technology imaging services.

This comprehensive review of the empirical evidence on physical self-referral indicates that these ownership arrangements have negative effects on utilization, costs, access, and quality. Specifically, the general consensus of all the available evidence is that the financial incentives that accompany physician self-

referral arrangements result in increased utilization of services and higher costs to patients. Moreover, physician joint venture facilities appear to cream-skim the patient with good insurance and thus treat relatively few indigent and underinsured patients. As regards geographic access, all physician joint ventures are located in metropolitan areas; hence, they do not, as claimed by proponents, increase access to services and new technologies to persons residing in medically underserved or rural areas. Finally, there is some limited evidence suggesting that joint ventures have adverse effects on quality. None of the evidence to date has been able to evaluate whether the increased utilization that accompanies the practice of physician self-referral represents inappropriate or unwarranted services. On the other hand, there is no evidence to date demonstrating that physician self-referral arrangements have any benefits to consumers.

The current law is based on extensive published empirical research documenting the negative consequences of physician joint ventures. Congress should be commended for enacting comprehensive legislation on the basis of good empirical research that has been published in the leading medical journals. Most researchers and policy makers recognize that the current law has a number of loopholes that limit its effectiveness. For example, because within office self-referral arrangements are legal, physicians can skirt the prohibition on referrals to freestanding facilities by putting diagnostic equipment or physical therapy in their offices. In fact, the current law has fostered the growth of clinics without walls. Also, the federal law does not apply to privately insured

patients, nor does it encompass all types of medical services. The current law should be reformed to eliminate such loopholes

The reforms suggested by those opposed to the current law will essentially make the current prohibition worthless. The reporting requirements of the current law are critical for enforcement and monitoring these abusive ownership arrangements. The claims by opponents that the current law is burdensome to physicians is based on anecdotal evidence. Moreover, no empirical evidence exists to support the contention that managed care will eliminate the increased utilization and higher costs linked to physician self-referral arrangements. Given that less than ten percent of Medicare patients are enrolled in HMOs, it is highly unlikely that managed care plans will be capable of resolving this problem.

In conclusion, any reforms that weaken the current law would result in increased utilization and higher costs for consumers. Thank you for providing me with the opportunity to testify here today.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

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 percent 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 percent 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 percent and the number of x-ray films per visit by 16 percent. The total charges per month, adjusted for inflation, grew 20 percent, 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, Noehter 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 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 JM, 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 60% 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.

Chairman THOMAS. Thank you very much, Dr. Mitchell. Thank the panel. Mr. Stark will inquire.

Mr. STARK. Thank you, Mr. Chairman. Dr. Mitchell, it would be self-serving to suggest that you got into this or got interested in this at any request of the Federal Government or this Committee. I believe that the State of Florida and some legislators in Florida got interested in this referral issue long before it came to the attention of this Committee; is that not correct?

Ms. MITCHELL. That is correct.

Mr. STARK. You might just, if you could in just a minute or so, summarize for the Chair and myself what was happening in general in Florida that perhaps got you going, got you started on these studies.

Ms. MITCHELL. Well, what happened was in 1989 this issue was brought to the attention of the House of Representatives in the State of Florida. In particular, in south Florida there were several joint ventures opening up and essentially cream skimming all the patients and dumping the Medicaid and the uninsured on the hospitals, and the hospitals essentially went to the Chairman of the Health Committee, Mike Abrams, and said look, this is a real problem. We need to have some legislation dealing with this. But the Florida legislature does not like to do anything unless they study the issue. So they commissioned this study, and I was contracted by the Florida Health Care Cost Containment Board to conduct the study.

Mr. STARK. Well, and I might ask you to further assuage the Chair's fears that some of these studies did not take into account the quality of treatment in the results. It is my understanding, having once attempted to write an article for JAMA, that they will not take work that is not very well researched or from someone who knows nothing about what they propose to write.

The research studies that you have provided really did attempt to see whether there was a change in practice, and whether the outcomes, to the extent that information is available, could be measured. I think this work would generally pass the highest standards of professional research.

I do not now, as you did, have any vested interest in this one way or the other, other than research that would stand the scrutiny of your peers in academia. I just wanted to qualify that most of these studies were not at the behest of the hospitals who now maybe have changed their minds because they want to get into the business or at the behest of the radiologists who are maybe losing patients or at the pharmaceutical companies or the doctors. This was a problem in general when you started doing research and not only yourself, but others studying it have not had a predetermined position. Do you want to—could you give us some further assurance that you are an honest researcher in this area?

Ms. MITCHELL. Mr. Stark, I can tell you that I worked for essentially negative wages when I was doing this study. It basically almost killed me. I have no vested interest in anything, and as an academic researcher, we are held to the highest standards. You know, the New England Journal only accepts about 3 percent of the articles that are submitted to it. The same is true of JAMA.

Mr. STARK. I am sure.

Ms. MITCHELL. You have four reviewers for each journal. It is all blind review. So, you do not know who these people are out there except that they are people who are qualified to review the material, and if your research is accepted in either of those journals, it has met the standards of the medical community that this is good research and solid empirical research. You cannot be published in any better journals than New England Journal and the Journal of the American Medical Association. It is all blind reviews, so they have no idea.

Mr. STARK. On the other hand, various groups can take your research and interpret it differently.

Ms. MITCHELL. Exactly as they want, yes.

Mr. STARK. I just wanted to reassert that this problem has a way of turning. Originally, the hospitals in Florida found they were being harmed. Now we have received testimony today that the hospitals got into the business.

I suspect that the other witnesses, the physical therapists and the radiologists would agree with the Chairman that we should define this better than we have and simplify the rules. We should chase after the administration to get the rules out more quickly, but I have never felt that physician self-referral was a problem that did not exist.

I think that the three witnesses here, Mr. Chairman, would indicate this. They are of the highest professional standing in the medical community or the medical service profession or in research they have confirmed that the Republican Inspector General originally suspected—that there is endemic in the medical care delivery a problem of unjust enrichment or overutilization; that there is an attempt to generate revenue; and that there is a new scam each year or a new innovation each year, if that is a better word to use. The laws ought to change in response. We should find a way to have a more rapid response.

I thank the Chair for bringing this excellent panel to the attention of the Subcommittee.

Chairman THOMAS. Thank you. In that regard, Dr. Mitchell, on page 6 of your testimony, the end of the first paragraph,

> None of the evidence to date has been able to evaluate whether the increased utilization that accompanies the practice of physician self-referral represents inappropriate or unwarranted services. On the other hand, there is no evidence to date demonstrating that physician self-referral arrangements have any benefits to consumers.

Ms. MITCHELL. That is correct. If you can cite me any I would be glad to know.

Chairman THOMAS. Well, no, I am saying if in fact none of the evidence to date has been able to evaluate whether the increased utilization represents inappropriate or unwarranted services——

Ms. MITCHELL. All we can say is that the utilization is much higher, significantly higher. If you were to determine whether——

Chairman THOMAS. Believe me, I understand.

Ms. MITCHELL. Actually I must qualify myself.

Chairman THOMAS. If I might, when you have those parameters for a study, any conclusions, such as, Mr. Grob's draw-your-own-conclusions, very often is not coming from the material if you cannot prove either of those basic points.

Ms. MITCHELL. Well, first of all, let me clarify this. No study has been able to determine that except for the California Workers' Compensation Study where they found that 38 percent of the MRI scans were deemed to be medically inappropriate when they were referred by self-referral physicians compared to 27 percent when they were not referred by physicians who had an investment interest. So, that is a significant difference in utilization because they were looking at specifically medical appropriateness. To have——

Chairman THOMAS. Question on that. Is it appropriate that someone who knows more about a medical technology might refer it more frequently and someone who spent so much time to learn about it that they thought it was appropriate to invest in it would probably have more knowledge and therefore refer more frequently than someone who did not?

Ms. MITCHELL. That is something you have to make a judgment on.

Chairman THOMAS. The answer on its face is, yes. But that does not necessarily prove——

Ms. MITCHELL. The financial incentive to refer is still there. I had doctors in the State of Florida who were making $400 in profit per MRI scan ordered the first year of business. I mean, that is outrageous.

Chairman THOMAS. I understand that.

Ms. MITCHELL. You tell me that physicians do not respond to financial incentive; they do.

Chairman THOMAS. As the Ranking Member said, we are interested in making sure, and I will state for the record, as I have already several times, that I have no interest in people unethically making money off of self-referrals. The question is whether or not the law as it now stands is as good as we can get it.

Ms. MITCHELL. It is not. It needs to deal with in-office, it needs to deal with private payers, it needs to have very stringent reporting requirements.

Chairman THOMAS. On page 6, in your testimony, you say all physician joint ventures are located in metropolitan areas.

Ms. MITCHELL. That was true in the State of Florida.

Chairman THOMAS. Is that a statement for all the United States?

Ms. MITCHELL. Well, let me ask you this, would you ever open a business in a rural area if no patients there? It does not make economic sense.

Chairman THOMAS. Excuse me, ma'am, you are the researcher whose credentials have been presented here as being unimpeachable in terms of your studies. I am looking at a statement in your testimony. It says all physician joint ventures are located in metropolitan areas.

Ms. MITCHELL. I should have clarified that, in Florida.

Chairman THOMAS. That is an unqualified statement of fact which I think you will find is refutable on its face, yet you make that statement.

Ms. MITCHELL. Well, that is true in Florida, I am sorry.

Chairman THOMAS. It did not say Florida in your testimony. Your unimpeachable professional credentials, which have been laid on the table, are the glasses through which I read your testimony and I did not see in Florida, I did not see in a portion of the coun-

try, I did not see in a particular region of the country, I saw a flat out factual statement which I believe to be inaccurate, and then again, draw your own conclusions and do not assume by my statement anything in motive at all. Dr. Templeton and Dr. Weinper, I invite testimony to refute the statement that with the passage of the law the universe of people who might be considered competitors has been reduced; is that correct? That prior to the law there were perhaps more people who could be in direct competition with you? After the passage of the law there are fewer.

Dr. TEMPLETON. No, sir, I do not believe that is correct in terms of this law deals with joint venture facilities. In my experience and in the experience of the American College of Radiology, by and large, those films are, in fact, read by radiologists regardless of the ownership. It does not deal with the impact.

Chairman THOMAS. Are other surgeons capable of reading the xrays?

Dr. TEMPLETON. In our opinion, they are not and in most surgeons' opinion they are not capable of reading those studies in those facilities. I think it is very unusual if not isolated instances in which the owners themselves actually participate in the interpretation of the studies, particularly MRIs.

Chairman THOMAS. But prior to the passage of the law, there was the opportunity for those individuals to exercise that if they felt so competent after passage of the law. If they do not, the universe is reduced. It is similar with the physical therapy as well, and so without indicating, as I have prefaced this whole statement in terms of motivation, there are those who could draw their own conclusion as to the rigor and the vigor with which you support the law, and I think that is a reasonable conclusion to draw from your willingness to testify in favor of retaining the law. It clearly shrinks the universe of those who would otherwise be seen as competitors, and I understand that. That is a perfectly legitimate reason.

Mr. WEINPER. In California many physicians provide physical therapy in their offices without licensed persons to do so, clearly in violation of State law, but do it nonetheless and get paid for it.

I know of no situation in California where a physician has divested himself or herself of a physical therapy operation due to Stark II. I do know of physicians who have mentioned the reforms in workers compensation which have made the national news. That makes it frankly not in their best interests to continue to do business because many times they are providing care in worker's comp environment.

Chairman THOMAS. It seems to me that that would best be treated as a malpractice issue, and there are whole areas of fraud and abuse that we can get into. I just wanted to indicate to you that someone looking at it from a slightly different perspective could draw a different conclusion.

Mr. STARK. Would the Chairman indulge me for a second?

Chairman THOMAS. Sure.

Mr. STARK. On page 6 of Dr. Mitchell's statement, you were concerned by the statement that all physician joint ventures are located in metropolitan areas. That statement refers to a specific study, Mr. Chairman, in which there were 1.3 million claims on the

previous page. There may be some syntax problems with it, but that statement of all physician joint ventures only refers to a particular study of 1.3 million claims and not the broad universe as you have suggested. If that statement is a very broad statement, I could understand the Chairman's objection, but to——

Chairman THOMAS. Well, I have to tell the gentleman, I have difficulty reading that direct transfer, when on page 5 there is a sentence that says specifically the general consensus of all the available evidence is that the financial incentives that accompany physician self-referral arrangements, is a universal statement dealing with all available evidence. Are you saying that refers specifically to the Florida study?

Mr. STARK. I am no one to analyze anybody's writing style, not the way this gentleman writes, but I have looked at it. Yes, what I am saying is that the phrase "all physician joint ventures are located in metropolitan areas" refers only to those joint ventures in that study which analyzed 1.3 million claims. Beyond that I would not——

Chairman THOMAS. On page 5 it says this comprehensive review of the empirical evidence.

Mr. STARK. And that this comprehensive review refers to the previous paragraph, the Florida joint venture study by Mitchell and Scott in 1991, their analysis of 1.3 million claims from Florida Medicare referrals, then this comprehensive review, and then it goes on. I did not mean to beg the question, Mr. Chairman, but I thought you might be more comfortable with Dr. Mitchell's credibility if I pointed that out.

Chairman THOMAS. Well, I guess in getting there I read through several other studies by the Federal Government which precedes that, and then there are references to these studies in several other paragraphs, but if we wish to break it down and grade it in terms of syntax and structure, we could take our own time to do that.

I have difficulty making the leap, but obviously you have drawn your own conclusions, and that phrase has been overused in this hearing. I want to thank the panel for their testimony. This is going to be an area which we will revisit with amendments, some of which my colleague will join in on, some I am sure he will not.

Just as we had great difficulty with the way the law was originally written, he is probably going to have some difficulty with the way in which the law is going to be changed, but I think you are going to find a kernel in there of general agreement which, hopefully, will allow us to continue to jointly make changes in this area so that no one can unethically make money off of self-referrals. I want to thank you very much for your testimony and contributions.

[Whereupon, at 1:25 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

TESTIMONY OF THE
AMERICAN ACADEMY OF NEUROLOGY
ON PHYSICIAN SELF-REFERRAL
BEFORE THE SUBCOMMITTEE ON HEALTH
OF THE HOUSE WAYS AND MEANS COMMITTEE
MAY 3, 1995

The American Academy of Neurology ("the Academy") appreciates this opportunity to present its views on issues related to physician self-referral. The Academy represents the interests of approximately 13,000 physicians Board certified in Neurology.

The Academy agrees that the problems with the current physician self-referral law identified by the Medical Group Management Association, the American Medical Association, and other organizations are ones which merit this Subcommittee's careful review. In particular, the Academy urges the Subcommittee to consider reform in the areas discussed below, which have a particularly adverse effect on the practice of neurology and appear to have little, if any, relationship to deterring abusive practices.

Site of Service Restrictions on Group Practices

The physician self-referral law restricts the ability of physicians in a group practice from providing ancillary services at more than one site. Thus, if a neurology group wishes to set up a diagnostic testing site for its patients in a rural area, it may not be able to do so. Although the law recognizes an exception for facilities in rural areas, the rural exception does not help where the main practice site is in a metropolitan area, but the group attempts to serve surrounding rural areas through satellite facilities. Thus, the law makes the development of ancillary facilities designed to bring more convenient services to patients in underserved areas extremely difficult. We do not believe there is any sound policy rationale for limiting the number of diagnostic sites physicians may develop for the convenience of their patients. We urge the Subcommittee to eliminate this arbitrary restriction on physician group practices.

No Exception for Bona Fide Shared Facilities

The law fails to recognize an exception for ancillary facilities shared between or among two or more physicians. We refer here to facilities jointly owned and run by physicians who practice in the same building, or even in the same office suite, and which are generally used exclusively for the physicians' own patients. These arrangements are cost effective ways for physicians to provide patients with needed ancillary services. In rural or underserved areas, in particular, where the hospital's resources are limited, it is often the only way to provide needed services. There is no exception for such shared arrangements under current law. As a result, patients often are required to travel to other sites for needed ancillary services, significantly increasing the cost and effort these patients must endure in obtaining needed care.

We realize that there is potential for abuse in this area but believe the law can certainly distinguish between abusive joint ventures and cost effective shared service arrangements developed by physicians who are on-site, involved in supervision of non-physician personnel, and utilizing the shared facility as an adjunct to their own office practices.

We urge that any bill modifying current law provide an exception for shared facilities.

Inpatient and Outpatient Hospital Services

The inclusion of inpatient and outpatient services in the list of designated health services has had the effect of needlessly complicating relationships between hospitals and physicians and increasing the cost of doing business with no corresponding benefit to society. As a result of the OBRA '93 amendments, everything a physician orders for a hospitalized patient becomes a potentially prohibited "referral" and must be analyzed to ensure it does not violate the law. Hospitals are already highly regulated by state and federal law. In addition, they are subject to cost control constraints from a variety of sources, including Medicare prospective payment. Hospitals have every incentive to be prudent buyers and to engage in cost-effective behavior. In addition, hospital quality assurance and utilization review provides another layer of protection against potential over-utilization associated with improper referrals. In fact, in our experience, the law often operates as an impediment to the hospital's cost-control efforts, because hospitals are unwilling or unable to contract with referring physicians, even though they may offer the best quality service for the lowest price.

Moreover, to the extent that there is likely to be collusive behavior between physicians and hospitals, the Medicare anti-kickback law, with its potential for criminal penalties, is certainly adequate legal deterrent. The restrictions in the physician self-referral law are simply not necessary. Other laws already provide adequate protection against potential abuse.

Therefore, we urge the Subcommittee to remove inpatient and outpatient hospital services from the prohibitions on physician self-referral.

Physician Compensation Formulas

The compensation test included in the definition of group practice is, in our view, a serious and unwarranted intrusion by the federal government into private business matters. Physicians practicing together as a group should be able to decide among themselves how they are to be compensated. Moreover, the law as written is so ambiguous that it is extremely difficult to determine whether or not an arrangement is legal. Therefore, we urge that the compensation test be eliminated.

Thank you for considering this statement. If you have any questions, please call our Washington counsel, Richard Verville or Rebecca Burke, at 202-466-6550.

Statement of the

American Academy of Ophthalmology

for the

U.S. House of Representatives

Committee on Ways and Means

Subcommittee on Health

hearing on

Physician Ownership and Referral

Mr. Chairman and members of the Committee:

My name is William Rich. I am an ophthalmologist in private practice in Falls Church, Virginia and the Chairman of the Federal Economic Policy Committee of the American Academy of Ophthalmology.

Ophthalmologists are physicians who provide primary and comprehensive medical and surgical eye care. The Academy is made up of nearly 20,000 ophthalmologists -- over 90-percent of the ophthalmologists in the United States.

We urge your examination of the important issues related to physician ownership of medical facilities and the referral of patients to these facilities. In particular, we urge your consideration of the impact of physician ownership and referral laws on physician's ability to adapt to the evolving health care system.

Background

The American Academy of Ophthalmology recognizes that managed care will continue to be a growing segment of our nation's health care delivery system. The Academy has been actively encouraging its members to participate in managed care arrangements and to provide primary eye care services. We believe that the key to ophthalmologists participation in such arrangements is the ability to provide comprehensive eye care. Comprehensive eye care includes the delivery of medical and surgical services, preventive services, refractions and eyeglasses and contact lenses.

Regrettably, ophthalmologists ability to provide comprehensive eye care is seriously hampered by provisions in OBRA '93 referral and ownership provisions known as Stark II.

Many managed care organizations will not contract with ophthalmologists that do not dispense eyeglasses and contact lenses. These managed care organizations seek to provide their enrollees with the convenience of "one-stop shopping" for vision care. Some ophthalmologists have been able to meet this demand by forming optical shops within their practices via the "in-office ancillary procedure exemption." In other situations, it would be more efficient for independent ophthalmologists in the same facility to open an optical shop. The Stark II provisions prohibit this second type of arrangement.

As a result of the Stark II prohibition, some of the Academy's members have not been able to compete for managed care contracts. Others have been forced to merge their practices. Some may be simply refusing to provide covered eyeglasses and contact lenses to their Medicare patients.

The Academy understands the increased emphasis on primary care including primary eye care. We believe our membership is anxious to participate. Unfortunately, efforts to provide primary eye care have been hampered by the Stark II provisions which prevent the efficient delivery of eyeglasses and contact lenses. The Academy believes it is inappropriate that, in effect, independent ophthalmologists are barred from working together to open optical shops.

It is our understanding that optical shops were mistakenly included in the Stark II provision's list of designated services. While eyeglasses and contact lenses were in an original draft of the legislation, that category was deleted later in the drafting process when the legislation was narrowed to apply to only Medicare and Medicaid covered services. We believe this category was deleted because eyeglasses and contact lenses are not normally covered by Medicare or Medicaid.

Currently, however, eyeglasses and contact lenses still appear to be covered by the Stark II provisions. That is because a provision of the Social Security Act identifies eyeglasses as prosthetic devices and the Stark language includes restrictions on such devices.

In various correspondence with HCFA, Congressman Stark has stated his legislative intent to exclude optical shops from the OBRA '93 provisions. The Academy supports this exclusion.

Recommendation

The Academy strongly recommends that optical shops be removed from the list of designated services included under the Stark II provisions. This could be accomplished by specific language excluding eyeglasses and contact lenses or by removing the prosthetic and orthotic categories.

Thank you for your consideration of this recommendation. I am pleased to have had the opportunity to present this statement to you.

Statement of the
American Academy of Otolaryngology - Head and Neck Surgery
to the
Ways and Means Subcommittee on Health
for the Record of the May 3, 1995 Hearing on
Physician Self-Referral

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) welcomes this opportunity to provide a written statement for the record of the May 3, 1995 hearing on physician self-referral. The AAO-HNS is very concerned about the implications of the physician self-referral law that was mandated by OBRA '89, expanded in OBRA '93, and modified by the Medicare Technical Amendments of 1994. While the spirit of the original law is to be commended, the ambiguities in the current statutory language and the failure of the Administration to publish regulations, has rightfully caused tremendous confusion and alarm among our members. We are grateful that the Committee has decided to review this issue. A brief description of our organization and recommendations to provide legislative and regulatory relief from aspects of the law which remain problematic follow.

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) is the national medical association of physician specialists dedicated to the care of patients with disorders of the ears, nose, throat, and related structures of the head and neck. We are commonly referred to as ear, nose and throat (ENT) physicians, but are formally known by our Greco-Roman name of otolaryngology or otorhinolaryngology. We have over 10,000 members worldwide, about 7,500 of whom are practicing physicians in the United States.

Otolaryngologists treat many primary care problems, including sore throats, ear aches, and allergies, in both children and adults, but we are also trained to perform the most complex of surgical procedures. Head and neck cancer, facial plastic and reconstructive surgery, and hearing and balance disorders are just a few examples of our subspecialty areas of focus.

Statement of the Problem for Otolaryngologists

1. DELAY. The Health Care Financing Administration (HCFA) has failed to publish regulations on this law even though the ban on physician self-referrals to clinical laboratories has been in effect since 1992 and the ban on the extended list of items and services subject to the law has been in effect since January 1, 1995. **The law is supposedly self-implementing, but absent federal regulations clarifying the many ambiguous sections of the statutory language, many physicians cannot be sure if they are in violation of the law even with the best of legal counsel.** We understand that HCFA is planning to issue final regulations on Stark I in the very near future, as soon as the draft clears OMB, where it is cued up, and plans to issue a proposed rule on Stark II by the end of the summer. The AAO-HNS and many members of the health provider community asked HCFA to delay enforcement of the law until final regulations were issued. HCFA declined, indicating it was not within its authority to issue a moratorium on the effective date. Clearly, it is within Congress' scope to delay the enforcement of this law until final regulations are issued. In addition to the needed amendments to the Stark physician self-referral law which are recommended below, **Congress should enact a delay in the effective date of law until at least six months after final regulations are issued. It is only fair to allow physicians and others a sufficient amount of time to ensure that they are not in violation of the law.**

2. DEFINITION OF REFERRAL. The statutory language does not sufficiently define the term "referral" and therefore at present could implicate all items and services payable under the Medicare and Medicaid programs in the ban on physician self-referrals. In fact, a recent reading of the statute by HCFA would imply this. **Congress should amend the law to make it absolutely clear that only those services noted on the Designated Health Services (DHS) list are subject to the ban.**

Audiological (Hearing) Testing: When Congress, as part of the Medicare Technical Amendments of 1994 deleted "other diagnostic services" from the section of the Designated Health Service (DHS) list in the physician self-referral statute that read "radiology and other diagnostic services," the AAO-HNS was hoping that this would put to rest any concern that audiological (hearing) tests were subject to the law. The intent of Congress was not to subject all diagnostic services to the ban on physician self-referrals, and this is reflected by the passage of the Technicals bill. Some of our members provide in-office audiological testing to their patients to detect and treat hearing and balance disorders. Physicians who provide these hearing tests in-office for diagnosis and treatment purposes should not be subject to the ban on physician self-referral as this was not the intent of the law and there is no indication that the provision of these services poses any special harm or risk of abuse to Medicare or Medicaid. **There are also other diagnostic services that otolaryngologists provide such as in-office allergy testing (not clinical laboratory) which are not on the DHS list, but which may be implicated in the law, by the lack of clarity regarding what constitutes a "referral" subject to the self-referral ban.** This remains of concern.

3. DEFINITIONAL PROBLEMS RE: PROSTHETIC DEVICES. Ambiguities in the statutory language and the absence of regulations could implicate hearing aids in the ban on physician self-referrals even though they are not specifically on the list of DHS, and Congress did not intend these items to be subject to the ban. Although hearing aids are not a Medicare covered item, they are paid for under certain circumstances by various state Medicaid programs. Current federal statute regarding optional Medicaid benefits, happens to list hearing aids under the category of prosthetic devices, along with Durable Medical Equipment (DME), for lack of its own category, even though clearly hearing aids and DME are not prosthetic devices. Does this mean that hearing aids are part of the ban on physician self-referrals because prosthetic devices are on the DHS list? Hearing aids are not a Medicare covered item, but if they were, how would they be classified? In preliminary conversations with HCFA staff, we got the impression that HCFA might classify hearing aids as a prosthetic device, even though they are not considered prosthetic devices by anyone professionally familiar with hearing aids. **An amendment to the Stark law clarifying that hearing aids are not prosthetic devices at the very least is recommended. Deleting prosthetic devices from the list of services subject to the ban entirely would be preferred as these items are not necessarily subject to abuse by virtue of physician ownership or interest.** The law as written would seem to favor non-physician suppliers over solo and group practice physicians. We would hope that Congress would not permit special economic interests to dominate the market, but would allow physicians to continue providing the highest quality care and services to their patients in the most efficient and economical manner possible.

4. GROUP PRACTICE COMPENSATION DISTRIBUTION FORMULAS. The statutory language has created a frenzy among physicians in group practices who would normally distribute compensation among partners in the group based upon the work and profits that those individual physicians generated for the group practice. It seems unrealistic for the federal government to dictate how physicians in group practice arrangements should distribute their profits. At present, physicians who are partners in a group practice could not receive individual compensation based upon their patient load. The requirements have proven to be unworkable not only for full partners but also for physician employees. It is impossible to apply the compensation test (that would provide for an exception under the law) fairly and uniformly across physician employees in tax exempt clinics, medical schools, and for profit groups. Physicians in single specialty group practices would have to be treated differently than physicians in multi-specialty groups, and physician owners who are also employees would need special treatment. All this, while physicians in solo practice are not subject to these same tests, does not make sense. **Congress should amend the law to eliminate these arbitrary requirements for group practice compensation arrangements.**

5. SHARED IN-OFFICE ANCILLARY SERVICES EXCEPTION. Many physicians share office space, equipment, employees, and general overhead, in order to promote economies of

scale, but prefer to maintain their own autonomy and billing numbers, rather than incorporating as a group practice. For all intents and purposes, they function as a group, but bill separately. The lack of an exception to the ban on physician self-referrals for shared in-office services has proven to be of serious concern to many physicians, including otolaryngologists. This Committee passed such a provision during last year's health reform debate, but it failed to pass the Congress as it was connected to the larger legislation of health reform. **We would urge that the Committee and Congress again act to provide for this exception for shared in-office service arrangements to the physician self-referral ban**. Independent physicians who may share an x-ray machine or other diagnostic testing equipment, or employees should not be subject to the ban on physician self-referrals by virtue of the existence of these types of cost-effective arrangements.

6. REPORTING REQUIREMENTS. Congress should eliminate these requirements as they are unnecessary and would prove to be unduly burdensome on the physician community and the regulatory process, financially and otherwise. HCFA has more than enough other tools to gather useful information on physician ownership and to strain out abusive arrangements.

There are several other provisions which remain of concern, but which are not discussed here, including special problems for physicians who own and treat patients at Ambulatory Surgical Centers, and for group practices who have more than one practice site. We understand that these issues will be addressed by organizations closer to these matter, and we likely will support their recommendations for legislative amendments to the law.

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) is most pleased to see this Committee's scrutiny of the current physician self-referral law, and welcomes amendments to the law in 1995 as outlined above. We look forward to working with you to resolve these matters.

For additional information, please contact Beverly Nissenbaum or John Williams at the AAO-HNS at (703) 836-4444.

STATEMENT OF THE AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION ON PHYSICIAN SELF-REFERRAL BEFORE THE SUBCOMMITTEE ON HEALTH OF THE HOUSE WAYS AND MEANS COMMITTEE

MAY 11, 1995

The American Academy of Physical Medicine and Rehabilitation ("the Academy") appreciates this opportunity to present its views on issues related to physician self-referral. The Academy represents the interests of approximately 4,000 physicians Board certified in Physical Medicine and Rehabilitation.

The Academy agrees that the problems with the current physician self-referral law identified by the Medical Group Management Association, the American Medical Association, and other organizations are ones which merit this Subcommittee's careful review. In particular, the Academy would like the Subcommittee to consider reform in the following areas, which have a particularly adverse effect on the practice of physical medicine and rehabilitation and which do little, if anything, to curb abusive practices.

Prohibition on Providing DME to Patients in the Office

Physicians practicing in the specialty of physical medicine and rehabilitation (known as "physiatrists") often see a wide variety of patients with mobility impairments resulting from injury or disease. These patients often need items such as canes, walkers, splints, or braces. Before the OBRA '93 amendments to the physician self-referral law, physiatrists were able to dispense these items in the office. This allowed the physician to evaluate the fit of the item and educate the patient as to its use. Because of the changes in the law effective January 1, 1995, physiatrists are now required to send their patients to a third party supplier for these items. For patients with mobility impairments, for whom even a trip to the physician's office can be a challenge, a second trip to a pharmacy or medical equipment supplier is an extreme inconvenience. We believe it makes little sense for a physiatrist to see a patient in the office suffering from joint pain or recovering from a hip fracture and not be able to dispense a cane or a walker.

We urge that the prohibition on providing DME through the office be eliminated.

Physical and Occupational Therapy

Physical and occupational therapy are an integral part of the practice of rehabilitation medicine. As a result, many physiatrists provide these therapies in their offices or clinics by therapists they employ or with whom they contract. This allows the physiatrist to better supervise the therapy and better monitor the patient's progress We are not aware that this has been an area of abuse in the past in our specialty. Nevertheless, the OBRA '93 amendments added physical and occupational therapy to the list of designated health services. As a result, physiatrists may no longer own therapy clinics and cannot even provide therapy in their offices unless they comply with one of the complicated exceptions to the physician self-referral law.

We urge that physical and occupational therapy be removed from the list of designated health services.

Inpatient and Outpatient Hospital Services

We also urge the Subcommittee to remove inpatient and outpatient hospital services from the list of designated health services. Many physiatrists have hospital based practices in which they provide services to hospital inpatients and outpatients. Thus, they are often in the position of ordering tests, pharmaceuticals, therapies, and other ancillary services for hospital patients. Because of the OBRA '93 amendments adding inpatient and outpatient hospital services to the list of designated health services, everything a physiatrist orders for a hospitalized patient becomes a potentially prohibited "referral" and must be scrutinized to ensure it does not violate the law.

This unnecessarily complicates relationships between hospitals and physiatrists and, in our view, is not necessary to curb abuse. Hospital quality assurance and utilization review and caps imposed by TEFRA are more than adequate to prevent over-utilization. Therefore, we believe hospital inpatient and outpatient services should be deleted from the list of designated health services.

Physician Compensation Formulas

Physiatrists in group practices who provide physical or occupational therapy must comply with the compensation test included in the definition of group practice. This test represents, in our view, a serious and unwarranted intrusion by the federal government into private matters. Physicians practicing together as a group should be able to decide among themselves how they are to be compensated. Moreover, the law as written is so ambiguous that it is extremely difficult to determine which arrangements are legal and which are not. For these reasons, we believe the compensation test should be eliminated.

Thank you for considering this statement. If you have any questions, please call our Washington counsel, Richard Verville or Rebecca Burke, at 202-466-6550.

AACC AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY, INC.

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STATEMENT OF THE
AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY
SUBMITTED TO THE
SUBCOMMITTEE ON HEALTH
FOR THE HEARING OF MAY 3, 1995

The American Association for Clinical Chemistry, Inc. (AACC) supports the current prohibition against physicians referring patients to clinical laboratories in which the physician has a financial interest. We believe the intent of the original legislation, to significantly reduce the ordering of unnecessary laboratory tests, remains valid. We also believe that the data gathered over the past few years, both by the government and private sector, support the need for this legislation.

The Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) performed a study in 1989, which found that patients of referring physicians who owned or invested in independent clinical laboratories received more services than Medicare patients in general. In fact, the study reported that such physicians ordered 45 percent more services, costing the Medicare program $28 million.

A 1991 study by the Florida Health Care Cost Containment Board confirmed these findings. In addition to lab services, physician owners were overutilizing diagnostic imaging services and physical therapy services. A followup study by the General Accounting Office (GAO) for this subcommittee, reported that physician owners had a higher referral rate for all types of imaging services than nonowners. The GAO concluded their report stating "we believe this analysis of referral for imaging services, together with our earlier analysis of referral patterns for clinical laboratory services, illustrates a broad potential for higher use and higher costs through self-referral."

The American Medical Association (AMA), which is the largest physician association, has testified before this subcommittee in the past stating that "physicians should not refer patients to a health care facility outside their office practice at which they do not directly provide care or services when they have an investment interest in the facility." And, a similar statement is listed in the AMA's Code of Medical Ethics. AACC agrees with the AMA's statement and recommends that the subcommittee maintain the self-referral prohibition on clinical laboratory services and other areas with documented referral problems.

By way of background, AACC is the principal association of clinical chemists--professional laboratory scientists--including MDs, PhDs and medical technologists. Clinical chemists develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations. The AACC represents clinical laboratory scientists and managers working in hospitals, independent laboratories and industries nationwide. The AACC's objectives are to further the public interest and educational activities and help maintain high professional standards.

Thank you for your consideration of our views.

Sincerely,

Peter Wilding, PhD
President, AACC

American
Clinical Laboratory
Association

TESTIMONY OF THE
AMERICAN CLINICAL LABORATORY ASSOCIATION
BEFORE THE SUBCOMMITTEE ON HEALTH
HOUSE WAYS AND MEANS COMMITTEE
May 3, 1995

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 testimony today, we would like to review the status of the self-referral law as it applies to laboratory services. Then, we would briefly like to review the basis for that prohibition. Finally, we would like to discuss our views on some of the modifications of the law that have been suggested.

I. Self-Referral of Clinical Laboratory Services Should Continue to be Prohibited.

Congress enacted the prohibition of 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 any other services at that time, it found that the record amply demonstrated the need for a limitation on self-referral of clinical laboratory services. Under that 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.

The prohibition on self-referral of clinical laboratory services has been effective for over three years. While it is impossible to measure precisely the impact of the law on utilization of laboratory services, preliminary evidence is that the law has helped to reduce clinical laboratory utilization. Recent information from the HHS Office of the Actuary, on expenditures for independent clinical laboratory services, shows that expenditures for laboratory services have declined in recent years. In fact, for 1994, independent laboratory expenditures were expected to be about 2.3% below what they were in 1993. This reduction is at least partly the result of the prohibition on self-referral. Recent statements by the OIG also confirm that the reduction in laboratory expenditures is due in part to the self-referral prohibition.

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 make significant changes in the law's prohibition on self-referral of laboratory services. Moreover, unlike other services that were added by OBRA'93, the market has now had an ample time to deal with (and respond to) the self-referral prohibition for laboratories. Indeed, the figures cited above suggest that the law has had an impact in controlling the utilization of clinical laboratory services.

Furthermore, although ACLA recognizes that some have called for removing certain services from the list of "designated health services" that were added to Section 1877 in 1993, no group that we are aware of has suggested that clinical laboratory services should be removed from the list of health services subject to the self-referral ban. In sum, given the increasing concern that is being expressed about increases in the utilization of services and the costs to Medicare, there is no reasonable justification for limiting the prohibition on self-referral as it applies to laboratory services.

II. There is Ample Support For Prohibiting Self-Referral of Laboratory Services.

When Congress passed the self-referral prohibition, it did so based on a number of significant studies. First, 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 the cost of such increased testing to the Medicare program was about $28 million for 1989, a figure that he stated was conservative. The OIG concluded that these facts were "quite troubling" and a "cause for concern to the Medicare program."

The OIG also cited an earlier study in Michigan which had found the average number of services per patient furnished in physician-owned laboratories was 20% higher than the average number furnished in *all* laboratories. Moreover, physician-owned laboratories furnished 40% more services, when compared to only non-physician-owned laboratories.

These studies were basically confirmed by a study that was later performed in Florida. That study found increases in clinical laboratory utilization among physician-owned facilities. Larger 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. Gross revenue per patient was about $38 for laboratories with referring physician-owners compared to just under $20 for non-joint venture laboratories.

ACLA recognizes that these studies do not specifically show that the clinical laboratory services performed at joint venture laboratories were unnecessary. Still, on balance, as in 1989, when the self-referral law was passed, there appears little justification for the higher utilization of laboratory services at physician-owned laboratories. The likely, and most plausible explanation, is that physicians responded to their incentives for increased profit by ordering more services. This has been the conclusion of virtually all those who have studied the self-referral issue.

Indeed, numerous government agencies and legislators have noted the inherent conflict created by self-referral. The American Medical Association, for example, takes the position that:

> When physicians refer patients to facilities in which they have an ownership interest, a potential conflict of interest exists. In general physicians should not refer a patient to a health care facility which is outside of their office practice and at which they do not directly provide care or services when they have an interest in the facility.

The Federal Trade Commission has also acknowledged that antitrust and competitive issues can be raised by the practice of physician self-referral. The Internal Revenue Service has also expressed concern about arrangements whereby non-profit hospitals enter into certain types of joint ventures with their medical staffs.

Other lawmakers have also acknowledged the problems created by self-referral. In his Comprehensive Health Care Reform Program, then-President George Bush noted that physician self-referral should be prohibited. The report noted that "physicians and other providers increasingly refer patients for tests or to diagnostic centers at which they hold some financial stake--a clear conflict of interest." Similarly, in May 1992, Congressman Kasich and then-Congressman Santorum introduced H.R. 5142, which would have amended the Social Security Act to extend the ban on physician self-referral to all payors and to radiology and diagnostic imaging services, radiation therapy services, physical therapy services and DME. In sum, problems relating to self-referral have long been acknowledged, especially in the area of laboratory services.

III. Limited Modifications May Be Necessary.

ACLA recognizes that some modifications may be necessary to ameliorate the technical problems that have been identified. However, ACLA believes the basic framework and purpose of the law is sound; therefore, any changes should be modest and limited. We recommend the following:

First, many of the problems that currently exist in this area would be reduced had HCFA issued final regulations implementing the law, as called for in the law itself. While ACLA recognizes that the various amendments and changes to the law have complicated HCFA's task, we urge the Subcommittee to ensure that the final laboratory regulations--which were issued in proposed form over three years ago, three years after the law's enactment--are issued as soon as possible. We believe this will help clarify many issues that currently exist in this area. We especially believe that these regulations will clarify many of the questions that have arisen in the area of compensation arrangements, which we recognize have created some confusion.

Second, because ACLA believes it is necessary for the law to establish a "bright line" standard, ACLA does not believe it would be helpful to include an "intent" standard in the law. As the recent case against the *Hanlester Network* has shown, "intent" is a very difficult issue to prove in these cases. Moreover, the self-referral law is not a criminal statute, it simply limits payment for certain services. Thus, an intent-based standard is inappropriate.

Further, ACLA is also very concerned about proposals calling for the inclusion of a new exception for shared laboratory services. In the initial law, Congress drew a bright line separating permissible referrals from those that lead to increased utilization and higher health care costs. Under the law, if the physician has an ownership or investment interest in an outside entity, he or she could not refer testing or other services to that entity. However, if the testing or other services were furnished in a physician's own office or in a group practice's office, then they were permissible.

Shared laboratories blur this distinction between physician's own offices and those that are outside facilities. In the shared laboratory situation, independent physicians jointly buy laboratory or other equipment, which they put in a medical office building. Each physician sends his or her patients' testing to that laboratory. Testing is not performed by the physician referring the patient, under his or her supervision or by his or her employees. Thus, a shared laboratory is not the typical in-office ancillary service, which is exempted under Section 1877's requirements, and, accordingly, a shared laboratory should not be exempt. Moreover, the physicians who own the equipment in a shared laboratory are not a group practice because they have not taken any action to integrate their practices; therefore, they are not exempt under the group practice exemption. As a result, ACLA is very concerned that the use of a shared laboratory exception could create a new loophole that would lead to increased utilization and higher health care costs.

Finally, ACLA recognizes that there is a concern that self-referral has limited the ability of integrated health networks and other managed care entities to obtain needed services. Because the law was not designed with such arrangements in mind, ACLA recognizes that the law may present problems in this area. If an exception is added for managed care plans, we believe it should be carefully crafted to ensure that it does not protect what are basically fee-for-service arrangements with the same incentives for overutilization that currently exist. We would be happy to work with the Committee in crafting an appropriate provision.

IV. Conclusion

ACLA appreciates the opportunity to comment on these self-referral issues. We would be happy to work with the Subcommittee on resolving these issues.

Statement of the

AMERICAN COLLEGE OF RADIATION ONCOLOGY

The American College of Radiation Oncology (ACRO) is a professional association of physicians specializing in radiation oncology -- physicians who provide direct, sustained hands-on care to cancer patients. Founded in 1990, ACRO currently has more than 1,500 members. Although there are many radiology professional and scientific societies, ACRO is the only organization that specifically represents the socioeconomic interests of radiation oncologists. ACRO's membership includes physicians working in all care settings: community hospitals, freestanding centers, and academic and research institutions. It includes the directors of leading university departments, freestanding facilities, and both large and small community hospitals.

ACRO appreciates the opportunity to submit testimony for the record to the Subcommittee regarding physician ownership and referral arrangements. Before turning to our specific concerns, however, we would like to describe briefly for the Subcommittee the role of the radiation oncologist in caring for patients with cancer.

THE JOB OF THE RADIATION ONCOLOGIST

Radiation oncology is a unique, hybrid specialty that uses technology to treat patients who have or have had cancer. The radiation oncologist uses radiation as the treatment for cancer rather than surgery or chemotherapy drugs. Depending on the state the cancer is in when the patient is referred, the radiation oncologist's goal is either to cure the cancer or to relieve pain and prolong life. Approximately 60% of all cancer patients require a radiation oncologist's services at some time during the course of their disease.

There are only about 2,400 radiation oncologists in the United States. Roughly half of our members work in hospital-owned facilities, either as hospital employees or as independent practitioners. The other half work in freestanding facilities, which are typically owned by the radiation oncologists themselves.

Radiation oncologists work strictly on a referral basis. After a diagnosis of cancer is made, the patient is sent to a radiation oncologist for examination and the rendering of an opinion as to whether radiation is an appropriate treatment for the patient. If it is determined that radiation would be useful, the treatment of the patient is planned, supervised, and carried out under the immediate direction of the radiation oncologist. During the treatment period, the radiation oncologist generally assumes responsibility for the overall management of the patient's medical needs.

Because radiation oncology is entirely dependent on referrals from the diagnosing physician, radiation oncologists themselves cannot engage in self-referral. Moreover, 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. Accordingly, there generally is limited risk of over-utilization of radiation oncology services.

PHYSICIAN SELF-REFERRAL IN RADIATION ONCOLOGY

Prior to the enactment of the Omnibus Budget Reconciliation Act of 1993 ("OBRA 93"), it was not uncommon for developers of radiation therapy facilities to offer ownership interests, sometimes at prices below fair market value, to internists, medical oncologists, and other referring physicians. Developers offered ownership interests so readily because they suspected that where a referring physician had a financial interest in a facility, the physician had a strong incentive to refer patients to that facility, regardless of the facility's quality, location, or charges.

In 1992 and 1993, ACRO testified before Congress about the dangers that physician self-referral posed to patient care and the growing distrust and suspicion that marred the physician-patient relationship. ACRO urged Congress to eliminate the conflicts of interest that are inherent in physician self-referral. Congress responded by enacting the physician self-referral amendments within OBRA 93, commonly known as Stark II. Most importantly, Congress included "radiation therapy services" among the list of designated health services that would be covered by the self-referral ban.

Research has concluded unequivocally that self-referral of cancer patients in radiation therapy (i.e., from diagnosing physicians to radiation oncologists) results in substantially higher costs as well as lower quality. According to a study of Florida radiation therapy facilities that was published in the November 19, 1992 issue of the *New England Journal of Medicine*, the frequency and costs of treatment at radiation therapy facilities where referring physicians had an ownership interest were 40 to 60 percent higher than at facilities without referring physician ownership. Moreover, personnel of joint-ventured radiation therapy facilities spent 18 percent less time in quality control activities than their counterparts at facilities without referring physician ownership. The study also found that no joint-ventured radiation therapy facilities were located in inner-city neighborhoods or rural areas, showing that physician self-referral does not improve access to care in otherwise underserved areas.

Existing Medicare-Medicaid anti-kickback statutes and safe harbor guidelines alone are inadequate to deter self-referral. Similarly, experience has shown that self-referral cannot be contained through voluntary ethical guidelines. Rather, federal legislation and regulations explicitly banning self-referral for radiation therapy services are needed to eliminate the threat to high-quality, cost-efficient cancer care. Thus, while some criticisms of Stark II are merited, the prohibition on self-referral for radiation therapy remains valid and important. At the same time, it is important that the Subcommittee maintain language that allows radiation oncologists to own, or have some other financial relationship with, the facilities at which they practice, because these facilities are in effect an extension of those specialists' workplace. Specifically, the Subcommittee must maintain the language included in 42 U.S.C. § 1395nn(h)(5)(C), which provides that:

> "A request by a . . . radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such . . . radiation oncologist pursuant to a consultation requested by another physician does not constitute a 'referral' by a 'referring physician'."

* * * * *

If the Subcommittee would like any additional information concerning this issue or if ACRO can assist the Subcommittee in any way, please contact our Washington representatives -- Guy Collier at 202/778-8016 or Eric Zimmerman at 202/778-8148 at McDermott, Will & Emery.

American College of Surgeons

FOUNDED BY SURGEONS OF THE UNITED STATES AND CANADA 1913

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PAUL A. EBERT, M.D., F.A.C.S.
DIRECTOR

May 3, 1995

The Honorable Bill Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
1136 Longworth House Office Building
Washington, DC 20515

Dear Chairman Thomas:

The American College of Surgeons appreciates this opportunity to submit comments for the record of the subcommittee's May 3, 1995, hearing on physician self-referrals.

The College issued a statement in 1989 on the subject of patient referrals to ancillary services. That statement expressed the College's firm belief that professional income should be derived from the patient services that physicians personally provide or supervise, not from the goods or services they prescribe. Furthermore, the College believes that referrals made to ancillary health care facilities in which a referring physician plays no role in ensuring the quality of services, yet which result in a profit to that physician, clearly run contrary to this ethical standard. The premise for patient referrals must be quality of care, and not financial gain.

However, it is important to consider circumstances in which a physician's investment in ancillary health care services is not detrimental to patient welfare. Indeed, there may be times when such an investment addresses problems of inadequate access. In medically underserved areas physician-owned laboratories, imaging centers, ambulatory surgical centers, and other facilities may be the sole source for important health care services. In situations where some degree of patient disability is involved, a patient's comfort and convenience may be a significant concern. Also, in the case of very expensive medical equipment, it may be necessary for a group of physicians to pool their finances in order to make a valuable health care resource available to patients in the local area.

There have been studies suggesting that physician investment in ancillary facilities encourage unnecessary duplication and overutilization of services, thereby exacerbating the escalation of our nation's health care costs. Therefore, the College continues to support the principles behind restrictions on physician self-referrals, as long as they are carefully targeted to address areas of proven abuse. However, as the Health Care Financing Administration (HCFA) attempts to implement these laws, and health care professionals attempt to interpret and comply with them (in the absence of written regulations), the problems inherent in any effort to legislate ethical behavior are becoming apparent.

Indeed, using a broad, regulatory approach to eliminate certain types behavior often has the unfortunate effect of eliminating the availability of other services and conveniences that truly serve the patents' best interest. Until we actually see HCFA's Stark II regulations, it is unclear just what sorts of problems the current effort will present. However, if we are to judge from the alarming material that surgeons and hospitals are receiving from those who offer legal advice on this issue, there is a real potential that these regulations could have an impact that extends well beyond the undesirable behaviors and costly practices that Congress intended to address.

We look forward with interest to HCFA's publication of the Stark I and Stark II regulations, and will work with the agency in an effort to minimize any inappropriate applications of these laws.

Sincerely,

Paul A. Ebert

Paul A. Ebert, MD, FACS

JOINT LETTER OF:
AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, et al

May 3, 1995

Protect Consumer Health and Tax Dollars: Preserve Ban on Physician Self-Referral

Dear Member of the House Ways and Means Health Subcommittee:

The House Ways and Means Health Subcommittee meets today in order to hear testimony on physician self-referral -- doctors referring patients to laboratories and services in which they have a financial interest. We are writing as consumer, labor and patient advocacy groups to urge you to protect the current ban on physician self-referral from recent industry initiatives to weaken or repeal these laws.

The ban on physician self-referral was included in the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) and prohibited physicians from referring Medicare patients to clinical laboratories in which the physician held a financial interest. OBRA '93 extended this prohibition to apply to both the Medicare and Medicaid programs, and included certain "designated health services" in the ban.

Physician self-referral laws provide vital protection for consumers. As documented below, self-referral clearly leads to excessive utilization. which threatens the quality of health care through unnecessary medical treatment and adds unwarranted expense to our already burdened health care system. While Congress is searching for ways to reduce spending in Medicare and Medicaid programs, repeal of the physician self-referral laws would result in millions of dollars wasted on excessive testing.

A multitude of studies have documented the abuses involved in physician self-referral:

- Patients of referring physicians who owned or invested in independent clinical laboratories received 45% more clinical laboratory services than all Medicare patients in general. ("Financial Arrangements between Physicians and Health Care Businesses," U.S. Department of Health and Human Services, Office of Inspector General, OIA-12-88-01410, May 1989)

- Physicians with financial interests in laboratories ordered 34% to 96% more tests than other physicians. ("Physician Self-Dealing for Diagnostic Tests in the 1980s: Defensive Medicine vs. Offensive Profits," M. Cooper, Consumer Federation of America, October 3, 1991)

- Doctors who owned imaging devices ordered imaging tests four times more often than doctors who did not. ("Frequency and Cost of Diagnostic Imaging in Office Practice - A Comparison of Self-Referring and Radiologist-Referring Physicians," B. Hillman, C. Joseph, M. Mabry, J. Sunshine, S. Kennedy, M. Noehter, New England Journal of Medicine, 1990; vol. 322; 1604 -1608)

- Physician-owned laboratories, physical therapy centers, and diagnostic imaging centers were found to have increased utilization and higher health care costs. ("Joint Ventures Among Health Care Providers in Florida," Florida Health Care Cost Containment Board, Vol. 2, September 1991)

- The volume and total charges of non-hospital MRI tests performed in Florida facilities, which were overwhelmingly joint venture facilities, were respectively 118% and 92% greater than the national average. In addition, the impact of physician joint ventures on medical costs for imaging, clinical laboratory services and physician therapy services resulted in over $500 million in additional costs. ("Impact of Physician Joint Venture Activity on Medical Care Costs in Florida," Z. Dyckman, Ph.D., Center for Health Policy Studies, Columbia, MD, January 1992)

- Physicial therapy was initiated 2.3 times more often by physicians with investment interests than by those without investment interests. ("Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self-Referral by Physicians," A. Swedlow, M.H.S.A., G. Johnson, Ph.D., N. Smithline, M.D., A. Milstein, M.D., M.P.H., New England Journal of Medicine, 1992, vol. 327; 1502-1506)

The complexity of self-referral law and the rapid changes in the health care market may require clarification of self-referral legislation in order to assist with compliance. However, Congress must not eviscerate the intent and strength of the original legislation in the name of "clarification" or "streamlining." In particular, Congress should not eliminate vital reporting requirements or delete entire segments of the designated health services currently in the legislation.

Sincerely,

Diane Burke
American Federation of State, County and Municipal Employees

Leon Shull
Americans for Democratic Action

Jeff Jacobs
American Public Health Association

Arthur Levin
Center for Medical Consumers

Judith Stein Hull
Center for Medicare Advocacy

Cathy Hurwit
Citizen Action

Mern Horan
Consumer Federation of America

Gail Shearer
Consumers Union

Sandra Harding
National Association of Social Workers

Laura Wittkin
National Center for Patients Rights

Martha A. McSteen
National Committee to Preserve Social Security and Medicare

Linda Golodner
National Consumers League

Jon Lawniczak
National Council of Senior Citizens

Blair Horner
New York Public Interest Research Group

Charles Inlander
Peoples' Medical Society

Lauren Dame
Public Citizen's Health Research Group

Ned McCullough
Service Employees International Union

Patrick Conover
United Church of Christ, Office for Church in Society

Anne Werner
United Seniors Health Cooperative

Edmund Mierzwinski
U.S. Public Interest Research Group

STATEMENT
OF THE
AMERICAN OCCUPATIONAL THERAPY ASSOCIATION

The American Occupational Therapy Association (AOTA) appreciates the opportunity to submit testimony on the physician self-referral prohibitions of the Social Security Act as passed under the Omnibus Budget Reconciliation Act of 1989 and 1993, particularly as they affect the delivery of occupational therapy to Medicare and Medicaid recipients.

AOTA represents the interest of over 50,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. Occupational therapy practitioners provide critically important services to millions of people of all ages each year -- including Medicare and Medicaid beneficiaries -- in hospitals, nursing facilities, outpatient rehabilitation clinics, psychiatric facilities and school systems; through home health agencies and the offices of independent practitioners.

The treatment goals of an occupational therapy practitioner focus on promoting independence, preventing further disability and maintaining wellness. Individuals experience a variety of functional problems relating to aging or health problems such as heart disease, cancer, arthritis, stroke or Parkinson's disease. The therapist's interventions are designed to assist individuals in overcoming or adapting to limitations imposed by their illness or injury.

In 1993, Congress expanded the ban on physician self-referral to include occupational therapy services. Excessive utilization associated with self-referral arrangements, supported by strong empirical data, was the basis for extension of the physician self-referral ban to a range of designated health services including occupational therapy services.

AOTA strongly supports the efforts of Congress through this federal self-referral legislation to eliminate opportunities for inappropriate utilization of health care services driven by economic incentives rather than medical necessity. We commend Congress for condemning unethical practices of physicians who abuse their patients' trust for personal financial gain.
We encourage this Subcommittee not to retreat from this important public policy, but rather to work for its implementation and strong enforcement.

Frustrations expressed regarding ambiguity of the law must be dealt with swiftly. We encourage timely promulgation and implementation of the necessary regulations to assist physicians in complying with this law. Implementation of this important public policy is now more important than ever in light of increased fiscal pressures on all levels of government to cut program costs. In 1993, the Congressional Budget Office projected a cost savings of $350 million over a five-year period by enacting a prohibition on physician self-referral for designated services provided through the Medicare and Medicaid programs.

Several Studies Support Findings of Abuse

The prohibitions, enacted by Congress, were the result of several studies on physician self-referral. Since 1989, ten major studies have appeared in professional literature, including the New England Journal of Medicine and the Journal of the American Medical Association, supporting findings of excessive utilization of designated services by consumers referred by physicians who own or invest in these services.

One of the first studies on physician ownership and compensation from health care entities to which they make referrals was mandated by Congress in 1988, and conducted by the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG). Findings indicated that patients of referring physicians who own or invest in clinical laboratories received 45 percent more such services than all Medicare patients in general. The OIG estimated this projected increase in utilization to cost the Medicare program $28 million in 1987 and projected costs of $103 million in 1995.

A 1992 study of California Workers' Compensation program conducted by William M. Mercer, Inc. found that if an injured worker received initial treatment from a physician with an ownership interest in rehabilitation services, that patient received a referral for therapy 66 percent of the time compared to a referral rate of 32 percent from physicians with no ownership interest in rehabilitation facilities. Findings from the study showed that the added incentive for investing physicians to refer to rehabilitation therapy generated approximately $233 million per year in services delivered for economic rather than clinical reasons.

Other studies also demonstrate abuses in the delivery of occupational therapy and other rehabilitation services. Physician referral abuses were also found in a 1989 study mandated by the Florida legislature and conducted by the Florida Health Care Cost Containment Board ("Board") to examine the impact of physician joint ventures in health care services on the cost, quality, and access to health care in Florida. Physician-owned physical therapy facilities provided 43 percent more visits per patient and generated 31 percent more revenue per patient. Thirty five percent more therapy visits were provided per patient in physician-owned rehabilitation facilities. A subsequent 1991 study by the Board found that physician self referral resulted in an additional $500 million in health care costs in just one year.

Physician Referral Laws Promote Competition and Patient Choice

The potential effects physician investment arrangements can have on quality of care, utilization of services, patient choice and competition between those who provide health care services must be scrutinized. Patients may not be referred to the facility that can provide the optimum level of services or quality of care. Rather patients may be referred for costly services that are unnecessary or excessive, and competition can be undercut when health care service providers are compelled to compete not on the basis of quality or price but on financial remuneration that flows, directly or indirectly, back to the referral source. Because these arrangements hold such significant potential for patient abuse and fraudulent billing of third party payers, it is incumbent upon ethical practitioners to avoid any arrangements or circumstances in which patient referral are contingent, directly or indirectly, upon financial remuneration to the referral source.

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. Patients are vulnerable in health care decision making because they lack the special knowledge required to judge the necessity for recommended care. The presence of illness or injury may make it difficult for the patient to engage in the type of self-protective bargaining behavior necessary to insure they are receiving all the information they need to consent to services. Self-referral presents an unnecessary conflict of interest that should be avoided in the health care industry. Directing the purchase of health services is something quite different from directing the purchase of other types of services.

Several Exemptions Recognize Existing Business Practices

Even though inappropriate utilization may occur, Congress nevertheless allowed for a number of exceptions to the law in recognition of existing business practices. Additionally exceptions can be created by the Secretary as long as these exceptions do not pose a risk of program or patient abuse. Considered among the 15 exceptions are the special concerns of rural providers and prepaid health plans.

The Department of Health and Human Services reports that many of these exceptions were specifically designed to accommodate the development of managed care plans, integrated delivery systems, and new health care networks which link doctors and hospitals. The OIG has testified that creating new, broad exceptions for managed care is difficult because the term "managed care" is not well-defined. Some "managed care" situations, like health maintenance organizations (HMOs) typically operate as prepaid plan where conditions of participation and rules of financing are well defined. HMOs typically remove physicians from financial incentives to refer patients to other ancillary services. But in the case of a preferred provider organization (PPO) arrangement, physicians and ancillary service providers may agree to accept a lower price for their services than those providers who are not part of the network, but these PPO physicians may also be owners of a rehabilitation service center, which is also part of the PPO network, and gain profits from referring patients to this entity. AOTA believes it is important to be aware of an attempt to disguise inappropriate economic gain under the claim of efficient use of health care dollars in various "hybrid" approaches to managed care.

The in-office ancillary exception exempts physicians (both group and solo practitioners) with ownership and/or compensation arrangements from the self-referral ban for most services provided in their offices if they meet a set of requirements. Included among these requirements is "direct supervision" of services rendered to patients. Recommendations have been made to replace this requirement with a "general supervision" requirement. AOTA opposes amending the physician supervision requirement. A loosening of supervision requirements can only exacerbate a circumstance which currently exists that allows unqualified personnel to render substandard care. Specifically, an OIG study found that rehabilitation services conducted by employees of a physician's practice, and billed to the physician's Medicare number, did not amount to appropriate rehabilitative care by qualified individuals in four out of five cases, resulting in $47 million in inappropriate Medicare payments in 1991.

Rather, AOTA strongly recommends extending current Medicare certification requirements, which apply to independently practicing occupational therapists, to physician offices which provide occupational therapy. Currently, all Medicare-certified providers, except physician offices, must meet specific certification requirements for providing occupational and physical therapy services. The OIG study estimated a cost savings of at least $235 million over five years if the same certification guidelines are applied to physicians.

AOTA is opposed to proposals to eliminate occupational therapy from the list of designated health services under the current statute. Numerous studies have shown overutilization of rehabilitation services in which physicians have a financial interest leads to a significantly higher cost to the payer. A comprehensive list of designated services prevents physicians from substituting some services for others that would not fall under the statute. Suggestions that inclusion of a service on the list of designated services can lead to underutilization because the patient's condition goes untreated suggests that physician's simply won't refer patients for appropriate care unless they have a financial incentive to do so.

Similarly, these provisions do not prevent physicians from investing in and owning rehabilitative care services, such as occupational therapy centers, as a growing area of the health care market. But we believe it is reasonable to provide some assurances to consumers that physicians will not misuse their referral powers for profit. This law provides assurances that investment and ownership interest will not impede good medical judgment. AOTA does not support extending the exceptions to physician ownership in hospitals to include ownership in other facilities.

AOTA opposes eliminating the reporting requirements under this law. This information is pivotal to ensuring compliance with the law and these reporting requirements are reasonable and necessary as demonstrated by the findings in the self-referral studies. Eliminating reporting requirements will gut the ability to monitor and enforce the law. We also oppose exemption of state laws governing physician ownership and referral.

Conclusion

As Congress attempts to control rapid escalation in health care costs including federal Medicare and Medicaid costs, it seems counterproductive to allow self-referral practices. With Medicare insolvency imminent, it is irresponsible to repeal a law that can save the Medicare program money.

The Association and our 50,000 members are committed to providing the public with quality occupational therapy services in a cost-effective manner. We applaud efforts to ensure proper utilization of health care services and the delivery of quality care by appropriately trained health care professionals. We will support and work to secure Congressional approval of constructive proposals to achieve those ends. We believe these physician-self referral laws demonstrate a willingness on the part of policymakers to focus on these important goals of promoting competition and providing necessary, quality care while protecting taxpayers against unnecessary health care costs.

We appreciate the opportunity to submit this statement for the record, and look forward to working with the Subcommittee on the issue of physician self-referral.

STATEMENT OF THE AMERICAN PHARMACEUTICAL ASSOCIATION

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, is pleased to present this statement in support of existing restrictions on the ability of physicians to refer patients to other health care providers in which they have a financial interest. The profession of pharmacy is the third largest health care profession with over 170,000 pharmacy practitioners, pharmaceutical scientists and pharmacy students. Over two billion prescription orders are written by physicians and dispensed by pharmacists each year. Our members have a direct and significant interest in the issue of physician self-referral.

APhA believes the original objective of Congress in enacting the limitations on physician self - referrals was and remains valid. There was ample evidence that the practice of self-referral presented clear financial conflicts of interest for physicians and resulted in increased utilization of a wide range of health care services and substantially increased health care costs. APhA supported the self-referral provisions applicable to Medicare beneficiaries and Medicaid recipients that were included in the Omnibus Budget Reconciliation Acts (OBRA) of 1989 and 1993. Although we realize that this area of law, especially when considered along with federal rules relating to the anti-fraud and abuse statutes, is highly complex and may require simplification, we support retaining the existing framework of the self-referral provisions. Congress must not retreat from the legitimate problems that it sought to address when it enacted OBRA '89 and '93.

We specifically ask your Committee to retain outpatient prescription drugs as a designated service to which the restrictions on physician self-referral apply. It is important to clarify that nothing in the existing law precludes physicians from dispensing prescription drugs to their patients if authorized to do so by state law.

The law does - and we believe properly - limit the ability of physicians to buy or otherwise have a financial interest in pharmacies. During the late 1980's, groups of physicians formed companies and bought pharmacies to which they referred their patients. These companies were sophisticated corporate entities that would identify one, two or perhaps three pharmacies in a community, recruit physicians in the community as investors and encourage referral to only those pharmacies which the corporation had purchased. The impact on other pharmacies in the community was both immediate and dramatic. Some pharmacies were driven out of business; others simply lost a significant number of their regular patients. A number of states enacted laws prior to 1993 prohibiting physicians from having an ownership interest in pharmacies. We do not want these kind of enterprises to resurface as they almost certainly will if pharmaceuticals are removed from the list of designated services under federal law.

The issue is not simply one of unfair economic competition. Our concern is also a matter of overutilization, increased costs to the health care system and to patients themselves and the potential threat to the best health care interests of the patient. Over three-fourths of all patient visits to physician offices result in the issuance of a prescription - a much higher proportion than any other ancillary service a physician may order. Thus, the potential abuse in terms of utilization and higher costs is greatest in the absence of restrictions of physician self-referral with respect to prescription drugs.

Where a pharmacist is employed in a pharmacy owned by physicians and where many, if not most prescriptions orders are written by the "owners", the ability of the pharmacist to make an independent assessment of the appropriateness of the prescribed medication therapy and to effectively consult with the prescriber may be compromised. In addition, our previous experience with those pharmacies that were physician-owned demonstrated that they usually stocked a less representative range of medications (typically brand name drugs rather than generic drugs) than non-physician owned pharmacies resulting in higher costs to third party payors and patients paying out-of-pocket. Our past experience also demonstrated that some physician-owned pharmacies refused to accept Medicaid and Medicare patients because of burdensome paperwork and reimbursement limitations, thus severely limiting access by patients who have the greatest need for the widest range of prescription drugs.

Pharmacists are the most knowledgeable health care professional with respect to drugs. They are also the most accessible of all health care professionals; the equivalent population of the United States goes into a pharmacy each week. Pharmacists are also selected as the most honest and trusted professionals year after year in the annual Gallup poll of twenty five professions. Pharmacists play a vital role in counseling patients and monitoring and managing their medication therapy. APhA does not want the important role that pharmacists have in the health care delivery system placed in jeopardy. We urge the Committee to retain outpatient prescription drugs as part of the list of services to which the existing self-referral limitations apply and to proceed with caution in considering revisions to the law.

APhA appreciates the opportunity to submit this statement and looks forward to working with the Committee on the issue of physician self-referral of outpatient prescription medication services.

Statement of the

AMERICAN SOCIETY OF ECHOCARDIOGRAPHY

The American Society of Echocardiography ("ASE") is a professional organization consisting of over 5,000 cardiologists, internists, pediatricians, anesthesiologists, surgeons, and cardiac sonographers dedicated to the pursuit of excellence in echocardiography. ASE membership bridges specialty and subspecialty barriers, and ASE is therefore able to provide useful input in a wide variety of situations where echocardiography and Doppler are used in the clinical decisionmaking process.

Over the past decade, ASE has been closely interactive with the Health Care Financing Administration ("HCFA") in the development and implementation of policies regarding coverage and reimbursement for echocardiographic and Doppler methods. Accordingly, ASE's membership is very interested in the physician self-referral law (commonly known as the "Stark Bill"), and in resolving the confusion that has arisen concerning whether echocardiography services may properly be considered a "designated health service." ASE requests that these comments be considered by the Committee and be made part of the record of its May 3 hearing.

Congress recently enacted a Medicare technical amendments bill (H.R. 5252), which revised several of the definitions of designated health services. As you know, Congress revised the category of designated health services relating to radiology services to clarify that the only diagnostic services covered under this category of designated health services are those that are radiology-related.

ASE understands that HCFA intends to include echocardiography as a designated health service under the category of "radiology services." ASE strongly disagrees with this position and believes that HCFA's apparent conclusion that echocardiography services are a subset of radiology services is wrong. Echocardiography services clearly and simply are not radiology services. Thus, we recommend that the Stark Bill be amended to either eliminate radiology services from the list of "designated health services" or clarify that services performed by non-radiologists (such as echocardiography services) are excluded from the Stark Bill's self-referral restrictions.

The most obvious evidence demonstrating that echocardiography services are not radiological services is the separation of the CPT codes for radiology services and echocardiography services in the American Medical Association's Manual of Current Procedural Terminology (the "Manual"). The CPT codes for radiology services (see CPT Codes 70010 - 79999) are listed in their own section of the Manual, while the CPT codes for echocardiography services (see CPT Codes 93307 - 93350) are listed in the "medicine" section of the Manual. This separation demonstrates that the medical community does not view echocardiography services to be a subset of radiology services.

Equally obvious and telling is the fact that echocardiography services are nearly always provided by cardiologists and cardiac sonographers, not by radiologists and general sonographers. In fact, in 1992, radiologists were responsible for only 2% of roughly $600 million in Medicare allowable charges for echocardiography services. Further, echocardiography is nearly always performed in cardiology departments, not in radiology departments. These distinctions are consistent with the separation of the echocardiography and radiology CPT codes in the Manual.

Of additional importance, nearly all research conducted and literature published in the specialty of echocardiography is attributable to cardiologists, not radiologists. This serves as yet further proof that echocardiography is, in fact, not viewed as a radiology-related service. Furthermore, although training in echocardiography is an American College of Cardiology-mandated component of all training programs in cardiology, this is by and large not true for radiology training programs. Consequently, echocardiography should not be viewed as a designated health service by HCFA under the category of radiology services.

Finally, ASE supported the revisions to the physician self-referral restrictions that appear in the Medicare technical amendments bill recently enacted by Congress. One of

these revisions was the elimination of the phrase "other diagnostic services" from the category of radiology-related designated health services. Thus, in enacting this amendment, Congress made it clear that the self-referral prohibition applies only to diagnostic services that are radiology-related. Historically, echocardiography has been treated by HCFA as a "diagnostic service" unrelated to radiology. In light of HCFA's historical treatment of echocardiography as a general diagnostic service and Congress' amendment to the Stark Bill to eliminate reference to "other diagnostic services," we believe that HCFA has no legal authority to treat echocardiography services as designated health services under the category of radiology services.

In sum, ASE believes that echocardiography services clearly are not radiology-related. Accordingly, ASE requests that Congress prevent HCFA from applying the Stark Bill's self-referral provisions to echocardiography services. Congress can accomplish this objective in the following ways:

- First, by amending the Stark Bill to exclude radiology services from the list of designated health services;

- Second, by explicitly excluding echocardiography from the category of radiology services in the list of designated health services; or

- Third, by clarifying that services performed by non-radiologists, such as echocardiography services, are excluded from the category of radiology services in the list of designated health services.

Thank you for your consideration of these views of ASE. If you have any questions concerning these important issues, please do not hesitate to contact ASE's legal counsel, Diane Millman, at (202) 778-8021.

American Urological Association, Inc.
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Statement to the
House Ways and Means Committee
Health Subcommittee
on **Physician Self-Referral**
May, 1995

The American Urological Association represents 8,500 urologists in the U.S. We appreciate this opportunity to express our views on the current provisions regarding physician self-referral under the Medicare statute. Referral of patients to facilities for the sole financial gain of physicians is not acceptable; however, "Stark II" appears to go too far and restricts reasonable arrangements as well as fraud and abuse.

We recommend that the "Stark II" self-referral provisions be modified to allow for reasonable accommodations for cost-effective and efficient sharing of equipment, utilization of specialized equipment, and certain dispensing of durable medical equipment.

"Stark II" covers a very broad area, involving many physician modes of practice that have been in place for years, despite little if any evidence that these specific arrangements promote inappropriate behavior or result in significant additional costs to the Medicare program. The data originally cited to enact the bans in "Stark II" are several years old and of limited scope or applicability to current concerns.

Further, these provisions prevent physicians, hospitals and other health care providers from developing economical alternatives to promote cost effective care, such as integrated networks. The pressures of managed care in the private sector and the Medicare program require a greater degree of flexibility to respond to financial constraints than is permitted under "Stark II."

Urologists, like other physicians, have pooled their resources to acquire expensive equipment which they share, realizing more cost savings than if each had purchased their own.

Urologists typically provide their patients with incidental pieces of equipment that are covered by Medicare as durable medical equipment (DME) or prosthetic devices. The potential interpretation of "Stark II" restrictions on providing such equipment and devices have caused considerable confusion and led many physicians to discontinue providing these needed services to their patients. Physicians should be allowed to dispense these items for the convenience of the patients and not for profit.

Similarly, shock wave lithotripsy (SWL) is often performed by the urologist in a hospital outpatient department or in free-standing centers. "Stark II" would permit some urologists to refer their patients to SWL centers in which they have a financial interest, but is unclear on others. The American Lithotripsy Society presented additional information on the need to clarify these provisions in its testimony to the Subcommittee.

The American Medical Association and the Medical Group Management Association have also presented specific recommendations for modifying "Stark II" with which the American Urological Association agrees in principle.

In summary, the American Urological Association urges Congress to consider amending the Medicare physician self-referral provisions to clarify and allow greater flexibility in sharing equipment, utilizing specialized equipment, and in providing durable medical equipment and prosthetic devices.

Thank you.

Jordan J. Cohen, M.D.
President

AAMC

ASSOCIATION OF
AMERICAN
MEDICAL COLLEGES

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May 17, 1995

Mr. Phillip D. Moseley
Chief of Staff
Committee on Ways and Means
United States House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

Dear Mr. Moseley:

The AAMC represents the 125 accredited United States medical schools, nearly 400 major teaching hospitals, over 90 academic and professional societies, and the nation's medical students and residents. I commend you for convening a hearing to receive testimony about the Stark self-referral laws and appreciate the opportunity to express my concerns about the current law and make suggestions for ways in which it can be improved.

The AAMC supports efforts to ensure that physicians do not refer patients to entities in which they have an ownership interest. The first Stark law was passed as a result of studies that showed that fraud and abuse is most likely to occur when there is an ownership interest. However, the present law - even for the vast majority of the medical community who agree with its intent and seek to comply - is in some cases excessively constraining and complicated. The AAMC recommends the committee consider specific changes to the law as described below.

1. Physician Recruitment
One aspect of the law has a particularly negative impact on teaching hospitals, and the AAMC urges that it be changed. An exception is currently provided in the law for physician recruitment "in the case of remuneration which is provided by a hospital to a physician **to induce the physician to relocate to the geographic areas served by the hospital** in order to be a member of the medical staff of the hospital. . .:" (emphasis added) It is a common practice for a teaching hospital to wish to recruit residents from outside its immediate geographic area. In some instances these hospitals wish to retain their individuals as members of their medical staffs upon completion of their training. Yet, because the exception applies only if a physician relocates to a new geographic area, some newly trained physicians recruited by teaching hospitals risk violation of the law if the recruitment involves even otherwise reasonable inducements. This probably is an unintended consequence of the law and should be corrected.

The additional comments that follow are of a more general nature and affect many practices of both teaching and non-teaching institutions and physicians.

2. In-Office Ancillary Exception
The exception for in-office ancillary services currently requires that services be furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or by individuals who are directly supervised by the physician or another physician in the group practice. The AAMC suggests that the direct supervision requirement be deleted and replaced with a requirement for general supervision. This would assure that the referring physician, or another physician in the same group, is available if necessary but does not need to provide direct supervision. Many health care professionals - including nurses, physician assistants and nurse practitioners - have the training and experience to provide ancillary services without direct physician supervision.

3. Prepaid Plans
The exception for prepaid plans should be expanded to include state-regulated plans and Medicaid plans.

4. Community Need Exception
The AAMC recommends that the law be amended to add a community-need exception for the medically-undeserved areas, whether in inner-city areas or rural locations. For instance, this type of exception might permit underserved communities to join together to purchase medical equipment that would not otherwise be available to residents in these areas.

5. Rental of Office Space; Rental of Equipment
The exceptions for rental of office space and rental of equipment provide that the leases must be for a term of at least 1 year. While we understand the possibility for abuses in the case of short term leases, the current law makes it virtually impossible for a contract to contain a clause that would allow for termination in less than one year, even for good cause. No one should be placed in the position of having to comply with the physician self-referral law by continuing an agreement which has turned out to be a bad decision for one or both parties.

6. Definition of "Designated Health Services"

The AAMC suggests that Congress consider whether the list of designated health services (DHSs) is overly inclusive and should be reduced. For instance, certain services such as radiation therapy provide little chance for abuse. To keep such services as DHSs goes far beyond the intent of the statute and may result in the elimination of many traditional, non-abusive arrangements for delivering health care.

Thank you for your consideration of the Association's views. We would be pleased to work with you to ensure that abusive referral practices are stopped, while allowing the majority of physicians to provide high quality health care without the fear that they may inadvertently be violating the law. If you have any questions, please have a member of your staff contact Jeff Sanders at 202-828-0057.

Very sincerely yours,

Jordan J. Cohen, M.D.

TESTIMONY ON

PHYSICIAN REFERRAL RESTRICTIONS

BEFORE THE

HOUSE WAYS AND MEANS SUBCOMMITTEE ON HEALTH

MAY 3, 1995

William B. Yarmuth
Chairman,
President &
Chief Executive Officer

Caretenders Healthcorp is a leading provider of home and community-based health care services to disabled individuals of all ages. Our company specializes in comprehensive home health care and adult day health care and serves patients in seven states. Approximately 36 percent of our current revenues is from serving Medicare beneficiaries.

Section 1877 of the Social Security Act, the so-called "Stark I and II" provisions, is intended to prohibit physicians from overutilizing designated health services in which they have a financial interest.

We are supportive of the intent and principles of the law; especially since it is now in effect and providers have made changes to be in compliance. Furthermore, we obviously want to be in compliance with the law. The strict letter of the law, however, imposes high barriers to absolute compliance and stiff penalties for a designated health service provider and physicians for inadvertent non-compliance. The basic problem is that the scope of the law goes far beyond detectable investments by referring physicians.

Our dilemma in complying with Stark II is based on our situation as a publicly-traded company which is too big to know each of our owners every day and yet too small to be have at least $75 million in shareholder equity to qualify for the general exception for our stock. Many providers are in a similarly difficult position.

Our testimony will focus on three specific interrelated problem areas for inadvertent non-compliance and recommended modifications for each. The problems are the following:

1. "Zero tolerance" of any indirect or direct investment relationship
2. Overly broad application to investments of extended family members, and
3. Impractical monitoring of prohibited investors.

Our best recommendation for each of these problems is to use a five percent ownership threshold, already established for Medicare and Medicaid purposes in section 1124.

In addition, we urge a moratorium on Stark II enforcement until final regulations are published.

1. "Zero tolerance" of any indirect or direct investment relationship

The primary problem confronting a provider our size is that the scope of Stark II prohibits even insignificant, unknown and indirect investment or compensation by a referring physician or his extended family.

It is difficult enough to monitor direct stock ownership of physicians. Subsection (c) of 1877 makes exceptions to the ban on physician referrals for investments in companies that are publicly traded and whose stockholder equity exceeds $75,000,000, or mutual funds whose assets exceed $75,000,000. This provision was intended to recognize that investments in such large companies and mutual funds are not likely to affect either the financial performance of the company or the referral decisions of the physician-investor.

The aim of this exception is appropriate. However, it creates an uneven and perverse application of the law. The unreasonableness is obvious by looking at extreme situations. There is no problem if a physician owns 100 percent of a designated health service provider with more than $75 million in equity to which he refers patients but there is a big problem if his brother-in-law owns a small mutual fund which has one share of our stock.

Caretenders, with over $16 million in stockholders' equity and over $51 million in revenues in 1994, does not meet the threshold for exemption, yet there is essentially no financial benefit to us or a referring physician from any form of a relatively small investment.

Furthermore, Stark II goes far beyond direct stock ownership of physicians to encompass broadly-defined compensation arrangements and common forms of indirect ownership, such as stock held in "street name" with a brokerage firm, small mutual funds and investment clubs. In fact, most shares of our stock are held in street name.

Even "good faith" efforts on our part to know of Stark II prohibited relationships can not assure full compliance at all times. It should be noted that there is some appearance of reasonableness in the use of a "know or should know" standard for the imposition of civil money penalties for the submission of a claim for service when there is any such relationship with the referring physician under (g)(3). However, this "know" standard is not used so that we can be reimbursed for our cost in serving the beneficiary and is undermined by the absolute requirement under (f), described more fully below, to reporting any such prohibited relationship.

Recommended Targeting Modifications

We recommend that section 1877(c) be modified to focus the law more directly on situations where a physician-investor could significantly affect his or her income and the financial performance of the provider to which referral is made.

The critical distinction is not between companies with above or below $75 million equity. The more important distinction should be between significant financial relationships and insignificant relationship.

Clearly, a physician-investor who owns one share of a company's stock will neither base decisions on that ownership, nor have an impact on the financial performance of the company. However, a 100 percent ownership relationship between a physician (or immediate family member) and provider of designated health services with a 100 percent ownership relationship is inappropriate. The question becomes: where should one draw the line?

There is precedence in Medicare and Medicaid law to support a five percent threshold. Section 1124 of the Social Security Act requires that owners of five percent or more of a Medicare or Medicaid provider disclose their ownership to HHS and state Medicaid agencies. The five percent threshold dates to the Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977. Furthermore, the SEC requires individuals and companies to report any investments and investors of five percent or greater. Thus, from the Federal Government's perspective, there is precedence for ownership of five percent or more as being "significant" and a greater motive for fraud and abuse.

We recommend usage of the five percent ownership or investment threshold and submit that it is sufficient to identify those physician-investors and providers who stand to gain from referrals.

A good, but less valid, alternative would be to ease the shareholders' equity threshold for the publicly-traded company exception. Specifically, we recommend setting the threshold no higher than $15 million. If such a threshold approach was used, consideration could also be given to allowing a revenue test as another way to qualify for the exception. An exception based on annual revenues is a simpler and more accurate assessment of a company's size and therefore, the likelihood that one physician could have a significant financial impact. A revenue amount, such no higher than $45 million (three times our recommended equity amount) would seem reasonable.

In addition, the "know" standard should be applicable for purposes of the provider being reimbursed for the cost of services rendered in "good faith."

2. Overly broad application to investments of extended family members

Few Members of Congress or potentially affected physicians and providers of designated health services realize that another way the scope of Stark II goes far beyond detectable investments by referring physicians is to stretch in financial relationships involving "immediate family." There is reason to believe that the regulatory definition of immediate family could reach to in-law and step-relationships, which sounds more like extended family.

For purposes of Stark I, the Health Care Financing Administration has proposed that immediate family means the following:

> "husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild."

Recommended Targeting Modifications

To address this problem we recommend an "either-or" modification. For purposes of a provider being reimbursed for services rendered in "good faith," either target the scope of Stark II to physician relationships or use a de minimis standard, such as our recommended five percent ownership threshold, regarding a reasonable list of family relationships.

3. Impractical monitoring of stockholders

For any provider our size, it is impossible to know the identity of every stockholder, at all times. Yet, section 1877(f)(2) imposes a "zero tolerance" requirement that we report, for every occurrence, the following:

> "the names and unique physician identification numbers of all physicians with an ownership or investment interest...or with a compensation arrangement...in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity."

As we mentioned above, Stark II goes far beyond direct stock ownership of physicians to encompass broadly-defined compensation arrangements and common forms of indirect ownership, such as stock held in "street name" with a brokerage firm, small mutual funds and investment clubs.

Shareholder registration does not indicate the occupation and family relationships of an investor. Furthermore, Caretenders cannot know the name, occupation, and relationships of every person who invests in a small mutual fund that holds Caretenders stock. Securities law allows an individual to withhold his or her name as owner of a stock. These owners are called objecting beneficial owners.

The onus should be on a physician-investor to know and comply with the law. We submit that a written notice, at least annually, by each company to each of its referring physicians

would constitute a reasonable effort to alert physicians to the law.

Recommended Targeted Modifications

We recommend two modifications to the law that, implemented together or alone, would better target the effect of the law and reduce unreasonable and impractical requirements.

Our best recommendation for this problem is the five percent ownership threshold. Specifically, we recommend modifying 1877(f)(2) in the following manner (current language is *italicized*; added language is in **bold**; deleted language is ~~stricken~~):

> *the names and unique physician identification numbers of all physicians with* ~~*an*~~ **five percent** *ownership or investment interest....*

At a minimum, the "know" standard should be used to reasonably hold providers liable for reporting prohibited physician relationships under Stark II.

Moratorium needed on Stark II enforcement until final regulations are published

It has been almost two years since "Stark II" was passed. Yet, HCFA has not even proposed implementing regulations that define the specific policies associated with Stark II. However, on March 31, 1995 the Office of Inspector General at the Department of Health and Human Services published a final rule with a comment period that sets forth the civil money penalty, assessment and exclusion provisions that will be imposed for violation of Stark II.

It should be emphasized that HCFA has not even finalized regulations for Stark I, enacted in 1989!

There are a number of areas where the law is unclear; providers need guidance from HCFA to be certain they are in compliance with its provisions. We urge the Congress to legislate a moratorium on enforcement of "Stark II" until such time that a final rule is published.

STATEMENT
OF THE GROUP HEALTH ASSOCIATION OF AMERICA
ON SELF-REFERRAL
FOR THE RECORD
WAYS AND MEANS HEALTH SUBCOMMITTEE

Group Health Association of America (GHAA) is the leading national association for health maintenance organizations (HMOs). Our 375 member HMOs serve 80 percent of the 50 million Americans receiving health care from HMOs today.

GHAA strongly supports efforts to eliminate unnecessary costs from the health care system. Through the efficient use of resources, HMOs have been leaders in making quality health care more affordable. Because fraudulent activities can undermine these achievements, our member HMOs are committed to continuing their active participation in efforts to prevent, identify, and end fraud and abuse. It is important to recognize, however, that laws designed to curb fraudulent activities in the fee-for-service sector, such as the self referral law, can unintentionally inhibit legitimate HMO activities.

The self-referral law was drafted in response to abuses in the fee-for-service system in which physicians can benefit financially from unnecessary referrals. Because HMOs combine the financing and delivery of health care services, they are in a unique position with regard to the self-referral law. Consequently, HMOs are structured in a way which mitigates against unnecessary referrals. While the health care system has evolved to include integrated delivery systems, the self-referral law does not recognize this development. As a result, the current self-referral law inhibits cost-effective forms of integration.

The challenge for lawmakers is to revise the self-referral law to prevent fraudulent activities while allowing for innovation and cost-effective integration in the health care system.

GHAA's statement includes:

- an explanation of the distinguishing characteristics of incentives inherent in HMO and fee-for-service health care delivery;
- the detrimental impact of current self-referral laws on HMOs; and
- GHAA's interest is refining the self-referral law to focus narrowly on its goal of preventing overutilization motivated by financial incentives.

Different Incentives under Fee-for-Service and HMOs

The self-referral[1] law was designed to prevent over-utilization of services under the fee-for-service Medicare and Medicaid programs. The premise of the law is that fee-for-service payment inherently creates incentives to provide services beyond those medically necessary in order to increase providers' incomes. However, by their very design, HMOs have systemwide incentives such as quality assurance programs and financial incentives that mitigate against over-utilization. Although the self-referral law was conceived as a cost-saving measure which would prevent fee-for-service practices that improperly increase program expenditures, it has unintended consequences when applied to HMOs. Because the law is broadly written, it prohibits HMO arrangements that provide incentives to provide quality, cost effective care in addition to fraudulent practices that increase costs and result in lower quality care.

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[1] 42 USC 1395nn

HMOs commonly pay providers on an at-risk basis, under which at least a portion of the provider's payment is fixed regardless of utilization. This type of payment mechanism removes incentives for over-utilization. However, these arrangements have led to concern by some that under managed care, unscrupulous providers would be incented to under-provide care in order to profit.

Under-utilization, defined as the failure to provide medically necessary services, clearly constitutes a breach of contract between an HMO and a provider who has agreed to provide health care services in exchange for compensation. Under-utilization also may constitute malpractice when failure to provide health services results in injury.

HMOs have a vital interest in ensuring that under-utilization does not occur. Research studies consistently indicate that HMOs' cost effective care is also high quality care.[2] HMOs carefully structure financial arrangements with providers to promote high quality care and to minimize the impact of individual high-cost patients on providers' payments. To limit incentives to under-utilize, financial risk is spread over groups of providers and/or patients so that costs associated with services needed by an individual patient have little impact on an individual providers payment. In addition, high-risk conditions or high cost patients often are carved-out of any financial risk compensation arrangement to ensure that providers receive appropriate payment for needed services. Stop-loss insurance or reinsurance also may be provided to ensure that providers' payments do not fall below the level necessary to cover the cost of providing medically necessary services. Finally, rarely is risk-based compensation to a physician based on utilization alone. Other common payment factors include patient satisfaction and quality of care.

Even when HMOs compensate providers on a fee-for-service basis, incentives within the organization mitigate against over-utilization. HMOs providing Medicare and Medicaid services are required to have quality assurance programs and undergo external quality reviews. Through these quality reviews, unusual patterns of utilization may be identified and addressed and best practices are shared and promoted.

HMOs and the Self-Referral Law

Under the physician self-referral ban, physicians are prohibited from making a referral to an entity for the furnishing of eleven designated health services if the physician, or an immediate family member of the physician, has a financial relationship with the entity.[3] A financial relationship includes ownership or investment interests, as well as compensation relationships. The list of eleven designated health services includes broad categories such as inpatient and outpatient hospital services, radiology, and clinical laboratory services.

While the self-referral law provides exceptions for HMOs with Medicare risk or cost contracts and federally qualified HMOs, these exceptions are not broad enough. Other HMOs are subject to scrutiny under the self-referral law because the laws apply to any payments made by Medicare or Medicaid. All HMOs that are not federally qualified or do not have a Medicare contract are subject to scrutiny under the self-referral law since there is no exception for Medicaid contracts and all HMOs are likely to have Medicare beneficiaries enrolled through employer group contracts (e.g. working aged and retirees). HMOs with beneficiaries enrolled

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[2] *See* D. Clement, S. Retchin, R. Brown, and M. Stegall, "Access and Outcomes of Elderly Patients Enrolled in Managed Care," 271 *J. Am. Med. Assoc.* 1487 (May 18, 1994); S. Retchin, D. Clement, et al., "How the Elderly Fare in HMOs: Outcomes from the Medicare Competition Demonstrations," 27 *Health Services Res.* 651 (December 1992); J. Preston and S. Retchin, "The Management of Geriatric Hypertension In HMOs," 39 *J. Am. Geriatrics Soc.* 683 (July 1991); N. Lurie, J. Christianson, et al., "The Effects of Capitation on Health and Functional Status of the Medicaid Elderly," 120 *Annals Internal Med.* 506 (March 15, 1994).

[3] 42 USC 1395nn

under such group contracts provide services for which Medicare is a secondary payor.

As the health care system moves toward more cost-effective mechanisms for the delivery of care, the development of vertically integrated systems has increased. Vertically integrated HMOs, which own designated health service entities such as labs and radiology facilities, offer such services directly when it is more economical than contracting for the services with an outside provider. Such organizations also may offer physicians a financial stake in the cost-effective practice of medicine through an ownership interest in the HMO. As explained earlier, the structure of financial incentives in HMOs provide no motive to over-refer for profit. Nonetheless, under the self-referral law, organizations with any degree of physician ownership cannot own designated health services unless they are section 1876 cost or risk contractors or federally qualified HMOs. Only half of the currently state licensed HMOs are federally qualified, and with the sunset of the employer mandate provision[4] of the HMO Act later this year, there will be less incentive for HMOs to seek federal qualification.

The self-referral law also creates problems where physicians have only contractual arrangements with an HMO that is subject to the law. Any provider agreement could be considered a compensation arrangement and therefore subject to scrutiny under the self-referral law unless it is otherwise exempt. Once a physician has a compensation arrangement with an HMO which is subject to the law, referrals to designated health services owned by the HMO are precluded unless the compensation arrangement complies with the physician incentive requirements.[5] These requirements, intended to address *under-utilization,* have the effect of limiting the amount of risk which physicians can accept for referrals. As a result, if an HMO operates, for example, a laboratory or radiology facility as a line of business, the contracting physician cannot refer to that entity unless his or her compensation arrangement meets the guideline of the, as yet, unpublished rule.[6]

Conclusion

In order to contribute effectively to controlling health care costs, self-referral and other fraud and abuse laws must recognize the evolution in health care delivery away from fee-for-service medicine and toward HMOs and other integrated delivery systems. HMOs achieve cost savings and ensure quality by keeping referrals within the HMO system. The self-referral law should be amended to protect legitimate, cost-effective arrangements for the delivery of quality care that do not have the potential to violate the underlying purpose of the statute -- to prevent increased Medicare and Medicaid costs due to over-utilization.

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[4] 42 USC 300e-9

[5] 42 USC 1395mm (i)(8).

[6] 57 FR 59024 (December 14, 1992).

TESTIMONY OF THE
JOINT COUNCIL OF ALLERGY, ASTHMA AND IMMUNOLOGY
ON PHYSICIAN SELF-REFERRAL
BEFORE THE SUBCOMMITTEE ON HEALTH
OF THE HOUSE WAYS AND MEANS COMMITTEE
MAY 3, 1995

The Joint Council of Allergy, Asthma and Immunology ("JCAAI") appreciates this opportunity to present its views on the prohibitions on physician self-referral. JCAAI is an organization whose sponsors are the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. It represents the interests of over 4,000 physicians Board certified in allergy and immunology.

JCAAI agrees that the problems with the current physician self-referral law identified by the Medical Group Management Association, the American Medical Association, and other organizations merit this Committee's careful review. In particular, JCAAI urges the Committee to consider reform in the following two areas, which have a particularly adverse impact on the practice of allergy and immunology and which, in our view, have no sound policy rationale.

Restrictions on Physician Compensation Formulas

JCAAI believes that the restrictions on physician compensation arrangements included in the definition of group practice should be eliminated. This provision has a particularly adverse effect on allergists practicing in multi-specialty groups and actually discourages allergists from joining medical groups. Most multi-specialty groups provide some designated health services through the office and, as such, must meet the law's exception for in-office ancillary services, which includes the compensation restriction prohibiting physicians in the group from being compensated based on the volume or value of their referrals. "Referrals" includes not just designated health services but any service the physician orders but does not perform. Thus, even though allergy injections and allergy skin testing are not designated health services under the law, if they are performed by a nurse, as they frequently are, they are "referrals" for purposes of the compensation test. This means that if the physician is practicing in a multi-specialty group, the allergist's compensation cannot include the revenue attributable to injections and skin testing which the allergist orders and supervises. In contrast, allergists practicing alone or in a group which does not provide designated health services need not be concerned with meeting the exception for in-office ancillary services, and thus the compensation test does not apply. This creates a disincentive for allergists to join groups and participate in more cost-effective practice arrangements.

We do not believe that Congress intended such a result when it passed the OBRA '93 amendments to the physician self-referral law. We further believe that the compensation test is an unwarranted intrusion by the federal government into traditionally private matters. Physicians practicing together in a group should be permitted to decide among themselves how they should be compensated. We urge this Committee to support the elimination of the compensation test. At the very least, we believe the compensation test should only be applied with respect to designated health services and not all "referrals."

Prohibition on Providing Durable Medical Equipment

Allergists often prescribe durable medical equipment ("DME"), such as nebulizers, for their patients with asthma, particularly children, and, on occasion, as a convenience to patients, allergists would make these items available through their offices. The OBRA '93 amendments to the physician self-referral law, which went into effect January 1, 1995, now prohibit this. We urge that this prohibition be eliminated and that physicians be permitted to provide DME items to their patients if they meet the criteria for the exception for in-office ancillary services.

Thank you for considering this statement. If you have any questions, please call our Washington counsel, Richard Verville or Rebecca Burke, at 202-466-6550.

April 28, 1995

Congressman Bill Thomas
Chairman of the subcommittee on Health
Ways and Means

Dear Congressman Thomas:

I wish to submit written testimony to your committee regarding the problem we are having with the "physician self-referral to a medical facility" part of the Omnibus Budget Reconciliation Act OBRA 1989.

I believe I speak for most nephrology (kidney disease physicians) in asking you and your committee to reconsider or at least promote an exemption to the broad meaning of the self-referral Act regarding nephrologists who own and operate acute dialysis facilities in hospitals. In this situation, if we admit a patient to the hospital because they are in need of acute dialysis (urgent dialysis), we are in effect self-referring. This legislation has paralyzed our ability to participate in cost-effective managed care arrangements.

I don't believe this is the intent of the legislation as the legislation was primarily presented to prevent fraud and abuse with physicians perhaps referring to laboratories, radiology facilities, some sort of investment that's really not in the purview of their specialty.

As you can see, acute dialysis is exactly what kidney physicians do. It is almost impossible to produce a fraud and abuse situation with the present Medicare/Medicaid set up for end-stage kidney disease. Any patient that is on chronic dialysis that needs to go to the hospital acutely automatically comes out of the pool of the chronic dialysis patients. The reimbursement for that particular patient is then withheld and physician compensation is actually taken out of the picture if the patient is referred to a hospital. It's actually to the physician's benefit to keep the patient out of the hospital rather than admit. It is only in the extreme necessity of illness where a patient must go to the hospital and dialyze. Again, this is what kidney doctors do. We must have control of the quality mechanisms for dialysis, the staffing mechanisms for dialysis, the timing mechanisms for dialysis, etc.,

etc. By disallowing us to own and operate these in-hospital facilities and not allow us to refer patients to these facilities, really limits the scope of nephrology to a significant extent.

More importantly, however, and the reason for this communication is the impossibility now of collectively bargaining with the payers. We are trying to form a single capitated system for all of kidney disease. We know this can be a very effective way for kidney physicians to participate in more cost-effective managed care arrangement.

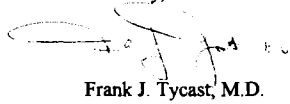
As you can see, we need to be able to offer the whole package. We cannot offer a managed care system complete kidney coverage for a specified price if we are not allowed to deliver or have any say in the cost and delivery of the acute dialysis situation in the hospitals. As it stands before the self-referral system law was passed, we were able to dramatically impact cost-savings because we were able to cross train dialysis personnel. Our nursing personnel would dialyze both in the hospital and the out-patient facility. We were able to efficiently use time and equipment so that the entire package would benefit both the payer and the payee. It was becoming a very efficient system until this self-referral ban as taken literally went into effect. This has caused us to stop our negotiations with the managed care system, it has doubled our overhead and we are trying to figure out a way to remain competitive and still offer a very quality product. It is my feeling and the feeling, I think, of most health care providers and economists that by disallowing the physician/nephrologist to own and operate the acute dialysis facilities in the hospitals, the Federal Government is actually "cutting its own throat" so-to-speak as now we will have to double the equipment, the people, the time, etc. I urge you to consider an exemption for acute dialysis in the hospital setting. Please allow nephrologists to operate these facilities and use these facilities in the hospitals as part of their entire system. We are finding it impossible to have any meaningful dialogue with managed care systems because now a large chunk of the entire kidney picture has been removed.

Lastly, as far as fraud and abuse potential for self-referral for dialysis patients is concerned, I think this is a theoretic problem only. I understand Congressman Stark has had phone calls from people indicating fraud and abuse. I don't know the motives for these calls but I frankly think it is almost impossible to create such a system. The rule is so oppressive for so little benefit that it really should be dropped in the case of acute dialysis patients. The margin of profit ranges in the several dollar amounts. It would take thousands of patients to be dialyzed for a single physician to create any significant fraud situation by referring patients to a hospital where he has facilities inappropriately. There are so many Medicare safeguards and hospital administration rules about length of stay and admission criteria, especially to dialysis units that we in Minnesota frankly find it impossible to admit patients without first satisfying very strict guidelines and dialyzing patients again without strict guidelines. As you may be aware, HCFA itself has very strong guidelines regarding who may and may not dialyze.

Therefore, Congressman Thomas, I hope you will read and disseminate this letter. I think we nephrologists very much need an exemption regarding self-referral to physician owned and operated acute dialysis facilities that are presently working very efficiently, very economically in the community hospitals. We cannot offer a competitive package to our managed care systems. It has put us in a very awkward position as far as delivering the entire package of kidney disease and the potential for fraud and abuse - I honestly believe almost non-existent.

Can you imagine a carpenter not using his own tools or a truck driver not allowed to drive his own truck, etc. This fraud and abuse problem is not the same as a physician investing in some nonrelated type investment where the physician would only refer strictly to that lab or that radiology department. This is so entirely different. I hope you can help us as the managed care systems in Minnesota are very much interested in our giving them the complete package. As it stands now, I believe this would be against the law.

Sincerely,



Frank J. Tycast, M.D.
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C. Everett Koop, M.D.

April 24, 1995

Subcommittee on Health
House Ways and Means Committee
Longworth House Office Building
Washington, DC 20515-6349

Dear Committee Members:

I have long been interested in banning physician self-referral for services provided to patients who are enrolled in the Medicare or Medicaid programs, and I would like to go on the record saying that I support the continued enforcement of the ban on physician self-referral for "designated services" provided under the Medicare and Medicaid programs, which went into effect on January 1, 1995.

Sincerely yours,

C. Everett Koop, M.D.
Surgeon General, U.S. Public Health Service (1981-89)

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May 1, 1995

Mr. Phillip D. Moseley
Chief of Staff
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20515

Re: Subcommittee on Health Hearing May 3, 1995, Concerning Self-Referral Provisions of the Social Security Act

Dear Mr. Moseley:

I am a health care attorney practicing in the Minneapolis area. I am actively involved in the American Bar Association and have appeared on several panels with representatives of governmental agencies dealing with antitrust, fraud and abuse, and the "self-referral" legislation (i.e., Stark legislation). I am writing on behalf of a radiation oncology group located in Minneapolis: Minneapolis Radiation Oncology, P.A. (MRO). I am submitting this statement for consideration by the Committee and for inclusion in the printed record of the hearing.

MRO has a staff of ten radiation oncologists and practices at seven radiation therapy facilities. Four of these facilities are owned by the physicians of MRO. The radiation therapy facilities that are owned by MRO typically have fee schedules that are substantially lower than those of radiation therapy centers owned and operated by hospitals. MRO has tremendously enhanced the quality of cancer treatment to patients in Minnesota and at the same time has made such treatment more cost effective.

ISSUE

The Stark legislation (42 U.S.C. § 1395nn) prohibits a physician or immediate family member of a physician to refer to an entity for the furnishing of radiation therapy services if such physician or family member has a financial interest in such entity. Your May 3rd hearing is intended to examine problems associated with compliance with the Stark legislation. The issue raised here is the prohibition of a medical oncologist to refer a patient for radiation therapy treatment to an entity in which such oncologist's immediate family member may have a financial interest.

CURRENT LAW

The prohibition found in 42 U.S.C. § 1395nn(a)(1) and the definition of a "financial relationship" found in 42 U.S.C. § 1395nn(a)(2) are expansive in attributing ownership of a physician to all immediate family members of such physician. The obvious rationale for having an attribution rule in this law would be to avoid physicians putting ownership in family members in order to avoid application of this law. For example, if a medical oncologist wanted to own a radiation therapy center he would simply be able to put the ownership in his wife's name (who does not work in health care) making it very easy for the oncologist to bypass the intent of the statute by conveying his ownership to her.

If, instead, the ownership of the radiation therapy facility was held in the medical oncologist's wife's name and such wife was a radiation oncologist, then the prohibition still applies. This is true even if the only practical choice is his wife for a patient needing radiation therapy and such referral is entirely within the scope of his practice.

The statute wisely contains an exception for referrals by a radiation oncologist to a facility owned by such radiation oncologist (see 42 U.S.C. 1395nn(h)(5)(C)). This exception recognized the lack of a conflict of interest that the radiation oncologist would have in such ownership. The exception, however, is not as expansive as the general rules in terms of "immediate family members."

PROBLEM

My understanding is that the Stark legislation emanated from Congressman Pete Stark's insistence that physicians were bilking the health care system. Notwithstanding that physicians are subject to "fraud alerts" and other indignities promoting to their patients their supposed lack of integrity, Congressman Stark felt the Medicare fraud and abuse rules were insufficient protections. The fraud and abuse rules make it illegal to pay or receive remuneration for referral. In discussions that my office has had with the Office of Inspector General (OIG) regarding referrals by a medical oncologist to a radiation oncologist's spouse, the OIG finds no problem with such referrals in the normal course of practice from a fraud and abuse standpoint. The Stark legislation, however, is absolute in its prohibition of such referrals. There is no requirement that a greedy or evil intent be present.

MRO had two radiation oncologists whose spouses were medical oncologists. Dr. Douglas Olson is one of the senior members of MRO and practices at a south suburban hospital. His wife is Dr. Barbara Bowers who practices medical oncology at a Minneapolis hospital. She is a dedicated practitioner in a most difficult field of medicine and several years ago was honored as one of the best physicians in the Twin Cities. This is testimony to not only the quality of her medicine, but her compassion with her patients and their families. Up until January 1, 1995 (i.e., the effective date of the Stark legislation), it had been a privilege for members of MRO to work with her in providing radiation therapy for her patients. Since that date, MRO has been required to reject all of her patients, almost all of which would be treated at facilities that Dr. Olson is not present. Dr. Olson's ownership in the practice does not allow Dr. Bowers to make referrals to any of their seven locations.

Another member of MRO was Dr. Graciela Garton. She is a talented and dedicated radiation oncologist that was recruited to provide radiation therapy services at a north suburban location. Her husband, Dr. John Garton, is a medical oncologist and was able to fill a position at the same hospital. Because of the Stark legislation, MRO was not able to accept referrals of Dr. John Garton's patients to MRO's radiation therapy facility at the hospital to which he was practicing. This resulted in an impossible situation for both them and their practices and, as a result, they left the Minneapolis area last month. The medical community at this hospital, after much searching and recruiting, lost two valuable members of its medical staff due to the arbitrary and harsh nature of this statute.

While it is not typical for married couples to both be physicians and refer to one another, it is certainly not that unusual. Many couples meet while in training and eventually get married. Because their training is in related fields and, as a married couple, they would practice in the same medical community, referrals between them would not only be typical, but almost unavoidable.

Aside from the intolerable situation it presents to practitioners in the field, the real ones hurt are their patients. A patient undergoing radiation therapy must endure daily treatments for up to five to six weeks. In addition, the patient is going through a traumatic ordeal with his or her cancer and is not feeling very well. Many are unable to drive on their own. All of these factors put a premium on convenience of geographic location of the radiation therapy facility. Dr. Barbara Bowers or Dr. John Garton would refer patients to an MRO facility if it was in the best interest of the patient. Due to the Stark legislation, MRO may no longer accept their referrals. Now their patients must literally drive past one of the MRO radiation therapy facilities every day for five to six weeks in order to travel to and from a more remote facility in order to get their treatment. This is a ridiculous result of government gone mad.

LEGISLATIVE PROPOSAL

While my first recommendation would be to repeal the Stark legislation in total, I would offer a specific change to the law as it pertains to the issues described above. The exception found in 42 U.S.C. § 1395nn(h)(5)(C) should be expanded to requests for radiation therapy services by family members of the radiation oncologist as well as the radiation oncologist him or herself. This particular provision of the law also deals with pathology and diagnostic radiology. There is no reason why a similar broadening of the exception would not apply to those areas of medicine as well. Therefore I would propose that this provision read as follows:

(C) Clarification respecting certain services integral to a consultation by certain specialists. A request by a pathologist (or an immediate family member of such pathologist) for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist (or an immediate family member of such radiologist) for diagnostic radiology services, and a request by a radiation oncologist (or an immediate family member of such radiation oncologist) for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician."

I would like to thank you and the Subcommittee on Health for holding this hearing to address a much needed area of concern. Thank you in advance for your consideration of the issues described above, as well as the proposed solution.

Sincerely,

Todd I. Freeman, for
LARKIN, HOFFMAN, DALY & LINDGREN, Ltd.

Statement
of the
National Association for Medical Equipment Services
on
Physician Self-Referral
for
Subcommittee on Health
of the
Committee on Ways and Means
Hearing
of
Wednesday, May 3, 1995

The National Association for Medical Equipment Services (NAMES) is pleased to provide this written statement for the record on physician self-referral and unfair competitive business practices within the nation's health care system.

NAMES membership comprises over 2,00 home medical equipment (HME) companies which provide quality, cost-effective HME services and rehabilitation/assistive technology to consumers in the home. These companies take pride in providing personal, comprehensive HME services in the setting where the vast majority of individuals prefer to recuperate — the home. HME consists of basic aids for daily living and a vast array of highly specialized and advanced services, such as infusion therapy for the provision of antibiotics and chemotherapy, oxygen and ventilator systems, wound care and ostomy supplies, and advanced rehabilitation equipment and assistive technology.

SELF-REFERRAL OF MEDICARE PATIENTS

In the recent past Congress has acted to eliminate the practice of physicians referring their patients to medical entities in which they had a financial interest. The Omnibus Budget Reconciliation Act of 1989 (OBRA '89) prohibited physicians (or their immediate family members) who have a financial relationship with clinical laboratories from referring Medicare patients to those entities, although a series of exceptions from the prohibition were provided. OBRA '90 created additional exceptions to the ban. Most recently, provisions in OBRA '93 expanded and clarified the self-referral restrictions.

In general, OBRA '93 broadened the physician self-referral statute to apply to both the Medicare and Medicaid programs. Furthermore, the ban now covers the following "designated health services" in addition to laboratory services:

- diagnostic radiology services;
- other diagnostic services (e.g., cardiology monitoring and muscle testing);
- physical and occupational therapy services;
- radiation therapy services;
- durable medical equipment;
- parenteral and enteral nutrients, equipment and supplies;
- prosthetics, orthotics and prosthetic devices;

- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

Clearly, the provisions in OBRA '93 reveal Congress understood some physicians were taking unfair advantage of their special patient-physician relationship by referring patients to their physician-owned ancillary services.

As the national association representing HME providers, NAMES supports the continued enforcement of the ban on physician self-referral for HME provided in the Medicare and Medicaid programs, which went into effect January 1, 1995.

NAMES was among the first groups to publicly endorse the physician self-referral laws. This was not an easy step for this association to take, given that our members' relationships with physicians are critical to the success of their businesses. However, the public policy reasoning and intent of physician self-referral laws are compelling and warrant the health industry's support as a step toward eliminating opportunities for abuse.

A number of studies and data support Congress' concerns in enacting a ban on physician self-referral. A 1989 General Accounting Office (GAO) study of Pennsylvania and Maryland clinical laboratory services indicated that both the utilization rate and average cost per service in physician-owned facilities was higher than that of non-physician-owned laboratories. Similarly, a 1989 HHS Office of Inspector General report concluded that patients of physicians with a financial interest in the entity to which they referred received 45% more clinical laboratory services and 14% more physiological laboratory services. The increased utilization of clinical laboratory services by patients of physician-owners cost the Medicare program an estimated $28 million nationally in 1987.

During the House Ways and Means Health Subcommittee October 1991 hearings on "Physician Ownership and Referral Arrangements", Congressman Pete Stark (D-CA) stated, "Physician ownership/ referral arrangements represent an exploding virus which ultimately will erode the trust that patients have traditionally placed in their physicians. The sad thing is that we are quickly getting to the point where each of us is going to have to wonder if we are getting a service because we need it, or because it would increase our physician's dividend check." This same concern exists with regard to hospitals which have a financial interest in ancillary medical services, such as HME.

ACQUISITIONS OF HME COMPANIES BY NON-PROFIT HOSPITALS

In recent years, many non-profit hospitals have established or acquired HME companies, ostensibly to provide "one-stop shopping" for people who are being discharged from the hospital. On the surface, such a concept may sound like a simplified, cost-effective approach to administering health care. This approach, which aims to eliminate the confusing bureaucratic maze of paperwork patients face when coping with a post-acute medical episode, could appear attractive at first. Yet, it has not taken long for many health care providers to determine that such "vertical integration" is **not** as wonderful as some claim and, in fact, has led, in essence, to "self-referrals."

The following problems either exist today or could occur for consumers, government agencies, HME providers and local communities due to hospital ownership of HME businesses:

- Non-profit hospitals may refer patients to their own HME companies, wherever one exists, without the patients having knowledge of other options — in other words, patients would not be given a choice of provider;
- Hospital-owned HME companies could drive existing independent HME providers out of business, thereby creating a monopoly situation that would allow hospitals to control the home care marketplace. Eventually, patients would have no choice available to them;
- Continued "self-referral" of Medicare patients could cost the government more money in the long run;

- Private pay patients who belong to a hospital-run health plan and are referred by the hospital for HME services could receive reduced care in order to allow the hospital to lower costs and save money; and

- There would be a loss of tax revenue as well as jobs within the community if non-profit hospitals eliminate for-profit independent HME companies from the marketplace.

LIMITED CHOICE OF PROVIDER

As noted above, one of the major concerns many Americans have regarding Congressional reform of our nation's health care system is whether they still will be able to choose their own health care providers. Physicians and non-profit hospitals which own HME companies and refer patients to them do not always provide their patients with a list of other HME providers in the area from among which to choose. As a result, those patients are unable to select an HME provider based on price and quality of care.

Consumer problems associated with physician self-referrals also were discussed as early as October 1991, in testimony presented by Mark N. Cooper, Ph.D., Director of Research for the Consumer Federation of America. At a hearing on "Physician Ownership and Referral Arrangements" held by the House Ways and Means Subcommittee on Health, Dr. Cooper testified that "the American people understand this problem well.... They find it difficult to shop for ancillary medical services. The reason is clear; since physicians order them, and physicians read them, consumers cannot and do not shop.... The American people want their doctors to be doctors, not to be profit makers by selling them ancillary medical services."

RECOMMENDATION

NAMES strongly recommends that Congress not only uphold all physician self-referral laws applying to HME, but closely examine the relationship between hospital-owned and independently owned ancillary services to determine the problems associated with this type of service delivery system. The repeal of physician self-referral laws would move the home medical equipment services industry in the wrong direction.

NACDS

National Association of Chain Drug Stores

NACDS Supports the Current Ban

The National Association of Chain Drug Stores (NACDS) supports current federal laws enacted as part of the Omnibus Budget Reconciliation Acts (OBRA) of 1989 and 1993 relating to the prohibition of physician self referrals for Medicare beneficiaries and Medicaid recipients for certain medical procedures and services to entities in which the physician has an ownership interest. We support the prohibition or ban especially as it relates to outpatient prescription drugs.

NACDS includes more than 160 chain companies in an industry that operates 30,000 retail community pharmacies. Providing practice settings for over 66,000 pharmacists, chain pharmacy is the single largest component of retail pharmacy practice. With retail sales exceeding $60 billion in 1994, chain drug stores represent 72 percent of the $82 billion retail drug store market. The NACDS membership base fills over 60 percent of the more than two billion prescriptions dispensed annually in the United States.

In summary, we believe that elimination of the self-referral ban on outpatient prescription drugs would adversely impact an individual's quality of pharmacy care, and would create an inherent conflict of interest for physicians who have a direct ownership or financial interest in an outpatient pharmacy operation.

Quality of Care and Conflict of Interest Issues

The Medicare program does not have an outpatient prescription drug benefit, but the Medicaid program does. In 1994, the program reimbursed pharmacies for approximately 340 million outpatient prescriptions. We believe that removing the ban on physician self referrals to outpatient pharmacies would have a negative impact on the health and quality of care outcomes of the Medicaid population, complicating the delivery of medical care to a population which already requires more medical services and procedures than the rest of the population.

Physicians with an ownership interest in a pharmacy operation have an incentive to increase the number of prescriptions they write for Medicaid recipients, prescribe more expensive but not necessarily more effective drugs, and refer recipients to pharmacies in which they have an ownership interest, even if there are closer and more convenient pharmacies.

Medicaid recipients often do not have the ability to travel long distances to pharmacies to have prescriptions filled, and should not be required or even directed to obtain pharmacy services from a physician-owned pharmacy operation. Unsuspecting Medicaid recipients might be susceptible to misrepresentations that they are required to use a certain pharmacy, without having the knowledge of the physician's ownership interest in that particular pharmacy.

In addition, because physician-owned pharmacies often have available only a limited number of prescription drugs, the Medicaid recipient may not be prescribed the prescription drug which is best indicated for the individuals's condition. Community retail pharmacies usually have a complete selection of prescription drug products, and can help the physician select the appropriate product for individuals. For all these reasons, quality of care is maintained with the current laws relating to physician self referral.

Pharmacy Services Widely Available All Across the Nation

Some physicians may contend that they want to establish pharmacies near their office practices because pharmacy services are unavailable in the local community. However, pharmacists are among the most easily accessible and efficient health care professionals in our health care delivery system. Recent data indicate that 94 percent of the American population has a pharmacy within five miles of their homes. Many of these pharmacies have home prescription delivery services, especially in rural and other remote areas.

Medicare and Medicaid Costs are Likely to Increase

Many studies and analyses have documented the increased cost to the health care system as a result of physician self-referral practices. For example, a 1991 study by the Florida Health Care Cost Containment Board found that physician self referral resulted in an additional $500 million in health care costs in just one year. As Congress attempts to control rapid escalation in federal health care entitlement programs, it seems counterproductive to allow for this self-referral practice to be permissible again in Medicare and Medicaid programs. In addition, NACDS is concerned that an inherent conflict of interest also exists in cases where physicians have dispensing pharmacies in their offices. This should become more of a concern to Congress as an increasing number of physician group practices, which could also dispense outpatient drugs, contract with states to serve Medicaid recipients.

Managed Care Arrangements Not Discouraged Under Current Law

To our knowledge, the current physician self-referral ban has not prohibited the development and growth of managed pharmacy care programs. Because of convenience and efficiency, over 82 percent of managed care plans contract with community pharmacies to provide pharmacy services to the plans' members. Managing pharmacy care requires that the physician and pharmacist interact to determine the prescription drug best suited to the patient's medical need, which is not necessarily the drug that is the stocked by a physician-owned pharmacy operation.

Conclusion

In conclusion, Mr. Chairman, NACDS supports the current law on the ban on physician self referral under Medicare and Medicaid especially as it relates to outpatient prescription drugs, and strongly urges that it be retained. We look forward to working with you on this issue, and ask that you call on us if we can provide any additional information.

STATEMENT OF
EDWARD E. BERGER, PH.D.
NATIONAL MEDICAL CARE, INC.
to the
COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH
MAY 3, 1995

PHYSICIAN SELF-REFERRAL SHOULD BE PROHIBITED FOR ALL PAYERS AND ALL SERVICES

General Policy Considerations.

In recent years, public policy makers, health care provider groups and health professional associations have moved decisively to eliminate conflicts of interest - real or potential - which exist when physicians have a financial stake in services or institutions to which they refer patients. This movement is rooted in the widespread belief that the special relationship of trust which must obtain between physician and patients dictates that **personal financial considerations should never color, or in any way influence, a physician's clinical decision making on behalf of a patient.**

Because a potential conflict is always present when the physician stands to profit by making a particular referral, such referrals are increasingly proscribed by canons of professional ethics, organizational standards of conduct, and State and Federal law. *Physicians should be paid for the clinical services they provide to patients, broadly defined to allow recognition of both direct and indirect patient care and evaluation,* but **should derive no financial benefit from services provided by other individuals or by institutional entities.**

It follows that, just as the physician should not engage in fee-splitting with other professionals to whom he/she refers patients, **he/she should also not own or have an equity interest in a facility to which referrals are made.** Each of these circumstances creates a financial interest for the physician which may affect the independence and quality of clinical advice and decision making, and which can unnecessarily increase health care costs.

The Potential Pernicious Effects of Physician Self-Referral.

There are three distinct types of pernicious distortions which are introduced into the health care system when physicians are in a position to profit from referrals they make:

1. Overutilization of services. When a physician shares directly or indirectly in the income from services provided pursuant to his/her referrals, there is a clear financial incentive to increase the number of referrals made. This is obvious in the case of classic fee-splitting, but the same dynamic is at work when the physician is the owner of an entity to which the referral is made. With a capital investment or supplemental income stream at risk, the physician may in some measure be incented to make referrals to shore up a facility. Overutilization translates directly into excess costs, and indirectly into compromised quality of care.

2. Quality of care subordinated to financial self interest. If potential income corrupts the physician's judgement concerning how and where the patient can be best served, the quality of care obviously suffers. This distortion applies to quality as measured by objective parameters of clinical outcomes, and also to more subjective considerations of patient choice, convenience, comfort and satisfaction. Again, with a capital investment or secondary income stream at risk, the physician may be tempted to direct referrals to protect his/her facility rather than to optimize care.

3. Market inefficiencies and cost inflation. When the referring physician owns or has a financial interest in the entity to which the referral is made, we have a financial transaction in which the seller and the buyer are for all constructive purposes one, with the resulting price extracted from the pockets of government, private insurers, and/or the patients themselves. **The price and quality comparisons expected of buyers in an efficient marketplace are fatally compromised;** the inevitable result is higher costs and lower quality than would otherwise be the case. A special case of this distortion is seen when service providers must employ or contract with physicians who are potential referral sources in order to operate; if the physician can threaten to go into business in competition with the provider, his/her **control of referrals is a potent force in negotiating economically inefficient and excessive payment rates.**

Physicians' use of the relationship of trust between doctor and patient to negotiate with providers for favorable contractual terms or to extract economic rents through offers of referrals - either to a facility owned by the physician or to one which employs him/her - is especially troubling. This behavior turns the doctor-patient relationship, depicted as an inviolable trust when that suits the moment, into a form of practical ownership wherein the patient becomes a commodity to be bartered in the physician's self interest.

A Ban On Self Referrals Should Be Comprehensive.

Up until now, Federal legislative prohibitions against self-referral arrangements have been limited in three ways:

1. They apply to Medicare/Medicaid referrals only;

2. They apply only to designated health services; and

3. Among other exemptions, they do not apply to physician group practices.

None of these limitations is good public policy. On the contrary, the failure to implement self-referral restrictions applicable to all payers, all physicians, and all services is a significant impediment to national efforts to control health care costs and improve care quality.

The prohibition should apply to all payers.

A self-referral prohibition limited to Medicare/Medicaid leaves the great majority of patients in our health care system unprotected and subject to the distortions inherent in self-referral arrangements. It adds an additional problem by encouraging, or at least condoning, exclusion of Medicare/Medicaid patients from some (i.e. physician-owned) facilities, thereby limiting their care options. **If the self-referral prohibition is payer-specific, patients covered by that**

payer are disadvantaged in terms of access to care and their right to choose. The appropriate remedy is a blanket prohibition, which eliminates the ills associated with self-referral and promotes broad access and the maximum amount of choice for all health care consumers.

The prohibition should apply to all physicians, including group practices.

The blanket exemption for referrals within a qualifying physician group practice creates an opportunity for physicians to dodge all of the restrictions imposed by the self-referral legislation, reap all of the financial benefits of what would otherwise be seen as illegal and/or unethical cross-referral arrangements, and profit from their control over the nature and quality of diagnostic tests performed and ancillary services ordered. The problem is particularly severe for multi-disciplinary group practices, some of which comprise extraordinarily extensive closed systems of cross-referral, and is exacerbated as the group practice becomes a holding company operating ambulatory surgical centers, diagnostic testing centers, clinical laboratories, chronic dialysis facilities, and even inpatient hospitals. Operating in the context of traditional fee for service payment, such practices are powerful engines for the generation of revenue through control of referrals. They need to be controlled.

The prohibition should apply to all services.

Finally, **there should be few if any service-specific exemptions from the self-referral prohibition.** In the past, Congress has acted to extend its limited prohibition to new services as evidence of abuse through overutilization is gathered. Some medical specialties have argued that they should be permitted to make self-referrals because their services are not readily susceptible to, or have not been demonstrated to result in, overutilization. But overutilization is only one of the several distortions and inefficiencies introduced by self-referral. Quality of care, patient choice, and market distortions which drive up total costs are at least as important.

The case of acute dialysis services.

The provision of acute dialysis services to hospital inpatients provides a graphic example of this problem, and deserves extended discussion as an example of the complex incentives invoked by self-referrals. There are two distinct kinds of "acute dialysis". First, patients with no history of ESRD sometimes experience acute kidney failure secondary to other conditions or as a result of systemic shock. The kidney failure may be temporary, in which case acute dialysis in the hospital can keep the patient alive until function is restored; or it may be permanent, in which case acute dialysis may be a precursor to chronic therapy or (for the terminal cancer patient, for example) simply a postponement of the inevitable. A unifying feature of this class is that the hospitalization will have been made by a non-renal physician, and the nephrologist is in the role of consultant. No more than 5% of acute dialysis treatments fall into this group. This class of acute treatments does not seem to pose a direct risk of excessive hospital admissions. However, the consultant nephrologist may choose to dialyze a terminal patient before he or she dies, providing no real benefit to the patient or family. Similarly, the consultant may dialyze a patient who could be treated by more conservative means. If the consulting nephrologist has a financial interest in the acute dialysis program, the risk of such inappropriate treatment is increased.

The second group of "acute treatments", comprising 95% or more of all acutes, consists of those provided to chronic

dialysis patients during inpatient episodes. The nephrologist is frequently the admitting physician in these cases. Because the established dialysis regimen cannot be suspended during hospitalization, treatment is provided in the hospital by the acute program. These are the "acutes" for which the issue of nephrologists' financial incentives has been widely debated: some analysts believe that nephrologists have been gaming their payment system (capitated for routine care, per-visit or procedure for inpatient care) and thereby unnecessarily increasing admissions; if the physician can profit from the acute dialysis program, the incentive to game the system is markedly increased. For this second group of "acutes", the conflict of interest potential lies in avoidable admissions, but there is little risk of unnecessary or inappropriate dialysis.

For the second group there is also a serious concern about conflicts in the relationship between the physician who holds an acute contract and the hospital. A hospital which gives its acute dialysis contract to a nephrology group can be reasonably certain of securing the bulk of the group's inpatient referrals - whether that contingency is addressed in contractual language or not. It would of course be an explicit violation of law to write such a contract. Yet physicians hold acute dialysis contracts, and in many cases receive increased acute payment rates from hospitals without any competitive pressure, all across the country. For the hospital, changing the contractor, or holding the price line, may raise unacceptable risks on account of the nephrologists' volume of inpatient referrals.

Where the hospital has a chronic dialysis program as well, this threat is magnified: a lucrative acute contract to the physicians may be one way to prevent them from taking their patients and setting themselves up as direct competitors by starting their own facility. Of course, well-organized and managed hospitals may have some countervailing forces (such as the ability to foster cross-referrals from other specialties), but those too are ethically questionable.

The only way in which quality of care becomes relevant to this discussion is in the context of hospitals demanding and enforcing good quality as part of an open and competitive contracting process. Acute dialysis is the hospital's responsibility. The fact that a contractor is Medicare-certified to provide chronic treatment in a facility does not guarantee anything about their ability to do good acute dialysis. And even if one had reasons for restricting acute contracts to operators of certified facilities, that would not be a reason for excusing otherwise unacceptable financial conflict of interest.

There should be an exemption for acute dialysis programs in rural or isolated locations where there is a dearth of alternatives for the hospital. Otherwise, there is no good reason for supporting an acute dialysis exemption, and as discussed above a number of striking reasons to oppose one.

Conclusion.

Physician ownership of facilities to which referrals are made is structurally and fundamentally pernicious. **The exploitation of the doctor-patient relationship for financial gain, and the treatment of patients as commodities in a financial transaction, are unacceptable.** No one class of physicians or specialty, and no one group of provider entities, is inherently more or less ethical or honest than others. We should not require overwhelming demonstration of the ill effects of self-referral arrangements in each distinct area of health services before we act to eliminate the structural problem.

Financial arrangements which promote or allow physician self-referral lead to:

- overutilization of health services;
- subordination of such concerns as quality of care, patient convenience, access, and satisfaction to the financial interest of the caregiver;
- market distortions which increase the cost of discrete health care services and total health system costs; and
- corruption of the essential relationship of trust between doctor and patient.

A general prohibition against self-referrals, applicable to all payers, all physicians, and all services is an essential component of any plan to control total health costs and improve both the prevailing standard for quality of care and the responsiveness of the health care system to patient needs.

TESTIMONY OF OUTPATIENT OPHTHALMIC SURGERY SOCIETY

The Outpatient Ophthalmic Surgery Society (OOSS), an organization composed of approximately 800 ophthalmologists dedicated to providing high-quality ophthalmic surgical care in various outpatient settings, is delighted to have the opportunity to present testimony before the House Ways & Means Subcommittee on Health regarding physician ownership and referral arrangements. A substantial number of OOSS members (approximately 350) own and operate ambulatory surgery centers that serve Medicare patients undergoing cataract surgery, and are therefore both intimately familiar with, and uniquely qualified to comment on, physician self-referral restrictions.

AMBULATORY SURGERY CENTERS

Ambulatory surgery centers (ASCs) are facilities that provide high-quality, cost-effective, same-day care for a wide range of surgical procedures. In 1992, over three million surgical procedures, some 30 percent of which involved ophthalmic surgery, were performed in ASCs.

ASCs save hundreds of millions of dollars for the Medicare program each year. Medicare payments to ASCs for outpatient surgical procedures are substantially lower -- in some cases by as much as 50 percent -- than payments to hospitals (both on an inpatient and outpatient basis) for the procedures. 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.

THE INTRAOCULAR LENS AND CATARACT SURGERY

Intraocular lenses (IOLs) 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.

PHYSICIAN SELF-REFERRAL

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. As discussed above, ASCs save the Medicare program hundreds of millions of dollars. A number of studies, including a noted Florida Cost Commission Review of physician self-referral, examined the issue 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.**

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

achieve control of the surgical environment (lacking in the hospital), convenience for their patients, and reduced costs. 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 laboratory or radiology services. **The surgeon is not a passive investor; a "referral" is not really taking place.**

We are pleased that services performed in ambulatory surgical centers have not been specifically delineated as "designated health services" under the Stark II legislation. However,

- **OOSS strongly recommends that physician self-referral legislation be amended to specifically exclude services provided by ambulatory surgical centers.**

As noted above, we do not believe that Congress intended to impose physician self-referral restrictions on ASC owners. **However, regrettably, the ambiguities inherent in the Stark II legislation enacted by Congress in 1993 prevent the legislation from achieving this goal.** In fact, it is our concern that the Stark II self-referral prohibitions are already being misinterpreted by HCFA, and are destined to have a variety of unintended consequences. Specifically, a recent Health Care Financial Ventures Report regarding intraocular lenses and self-referral prohibitions suggests that HCFA considers the implantation of an IOL as within the scope of the physician self-referral ban. We strongly disagree. Accordingly, OOSS urges Congress to clarify this important measure before HCFA promulgates regulations.

The question of whether the physician "self-referral" provisions set forth at Social Security Act § 1877 are applicable to prosthetic devices and intraocular lenses implanted in conjunction with surgical procedures performed in ambulatory surgical centers for Medicare and Medicaid patients first arose because the physician "self-referral" provisions in § 1877(h)(6)(H) of the Social Security Act apply to "prosthetics, orthotics, and prosthetic devices." **This provision, however, should not be interpreted to trigger the application of the self-referral provisions to ASCs since the implantation of these devices is merely incidental to the performance of ASC facility services.**

Instead, IOLs should be considered a component of ASC facility services and not a prosthetic device, especially for physician self-referral purposes. We understand that the definition of "prosthetic devices" included in § 1861(s)(8) of the Social Security Act creates some confusion. This provision defines prosthetic devices, for coverage purposes, as follows:

> Prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; . . . (Emphasis added).

This provision, however, does not specifically define the intraocular lens itself as a "prosthetic device;" rather, this provision defines as "prosthetic devices" certain "conventional eyeglasses or contact lenses" furnished after cataract surgery.

Furthermore, ASC facility services are covered under a completely separate coverage provision than "prosthetic devices." Specifically, ASC facility services are covered under Social Security Act § 1832(a)(2)(F), while "prosthetic devices" are covered as "medical and other health services" under Social Security Act § 1861(s)(8).

Section 1833(i)(2)(A)(iii) of the Social Security Act specifically defines the ASC facility rate, or standard overhead amount, to include the IOL payment. In fact, the governing statute in § 1833(i)(6) authorizes civil monetary penalties for anyone who separately submits a claim for an IOL implanted in an ASC. Likewise, the implementing regulations (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.

We also note that Congress has established the payment rate for IOLs implanted in ASCs at $150. For this reason, ASCs' provision of IOLs does not pose any potential for abuse: ASCs' charges for IOLs are strictly limited by this Congressional mandate to 80% of $150 (or $120), with the Medicare beneficiary responsible for the remaining $30 copayment. **Under these circumstances, it is clear that applying the "self-referral" restrictions to IOLs implanted in ASCs would not serve any useful public policy objective.**

Finally, any application of the physician "self-referral" provision to IOLs implanted in ASCs could have a substantial -- and 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 that the implantation of an intraocular lens during cataract surgery does not represent the provision of the designated health service ("prosthetic devices"), triggering Stark II referral restrictions.**

EYE GLASSES AND CONTACT LENSES

As noted above, the provision of prosthetic devices constitute a "designated health service" under Stark II. While the services of an optical shop maintained by a physician are not identified as designated health services (indeed, optical shops were specifically removed from the legislation by the Subcommittee prior to final passage), another section of the Medicare law, delineated above, defines prosthetic devices as including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens. **HCFA has indicated that it likely intends to interpret the phrase "prosthetic devices" to include "eye glasses or contact lenses," essentially prohibiting physician ownership of optical dispensaries.**

This is an egregious example of legislative overreach. There is no evidence of which we are aware that a physician is more likely to order eye glasses 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. Moreover, patients are certainly aware of the myriad of alternative sources of eye glasses and contact lenses from national chains to local opticians.

- **OOSS strongly recommends that Congress clarify that the Stark II legislation was not intended to encompass the provision of eyeglasses or contact lenses dispensed by physicians who operate optical dispensaries. This can be accomplished by adding "(except that such terms do not include intraocular lenses, eyeglasses or contact lenses)" after the notation of the designated health service, "prosthetic devices and orthotics and prosthetics."**

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The Outpatient Ophthalmic Surgery Society appreciates the opportunity to present this testimony before this distinguished Subcommittee. Please do not hesitate to contact Washington counsel, Michael Romansky, at (202) 778-8069 if you have any questions about this matter.

TESTIMONY OF SURGICAL CARE AFFILIATES, INC.

We appreciate the opportunity to submit testimony to the House Ways and Means Subcommittee on Health, and applaud the Chairman's recognition of the various problems created by the physician self-referral law, as well as his initiative in working with the industry to implement the law in a fair and effective manner, particularly with respect to managed care arrangements.

INTRODUCTION

Surgical Care Affiliates, Inc. (SCA) is the nation's largest independent operator of ambulatory surgery centers (ASCS). It is headquartered in Nashville, Tennessee, operates 63 centers in 22 states, and has operations in 28 of the top 50 HMO markets in the United States. During 1994, the company's centers provided outpatient surgical services to over 190,000 patients.

SCA's centers historically furnished outpatient surgical services independent of their hospital outpatient surgery counterparts. Efforts within the industry to reduce costs, a growing managed care market, and the formation of integrated health care networks, however, have encouraged hospitals and other providers to integrate their services with those furnished by SCA's centers. This has resulted in maximizing efficiencies and providing quality surgical services at the lowest possible cost. Accordingly, SCA's business strategy, which primarily has involved a partnership between the company and physicians within a local community, has evolved to include other health care providers and payors, such as community hospitals and HMOs. SCA views these types of partnerships as necessary within today's managed care market, and, in addition, believes these types of arrangements are critical to achieving efficient delivery of health care services and reducing the nation's overall health care costs.

SCA recognizes the problems that the Stark II physician self-referral law seeks to address. At the same time, it recognizes that physician ownership of ASCs has been shown to be beneficial, and Congress, therefore, has determined not to ban that relationship. Expanding beyond the physician-ASC relationship in the context of integrated health care delivery networks, may, however, be problematical. Certain ambiguities in the law could permit enforcement and other regulatory officials to interpret the law effectively to prohibit ASCs (and other independent outpatient health care providers) from participating in health care networks when, in fact, services furnished by ASCs (and other similar outpatient providers) were never intended to be covered by the law. The mere uncertainty that results from these ambiguities inhibits investment in the market and discourages the development of a managed care environment.

Accordingly, we urge the Subcommittee to pass legislation that would clarify these ambiguous provisions and assist in the promotion of managed care arrangements. In particular, we urge that (1) surgeons who request surgical services for their own patients be specifically exempt from the law consistent with the existing exemption for nephrologists, radiation oncologists, radiologists and pathologists; (2) the ban on "inpatient and outpatient hospital services" be deleted or clarified to make certain that ambulatory surgical services are excluded from that ban; (3) the ban on "radiology services" be clarified to make clear that it does not apply to those ambulatory surgical services that utilize an "imaging" device, which often is merely a video camera, in performing the surgical procedure; and (4) enforcement of the law be delayed until implementing regulations are promulgated.

APPLICATION OF "STARK II" TO ASCS

The federal physician self-referral law, commonly referred to as "Stark II," applies to certain "designated health services" set forth in the law, and does not specifically apply to ASCs. The law has never been intended to cover ASCs for various reasons. ASC services are not subject to abuse, such as over-pricing, since Medicare controls these costs by reimbursing ASC services on a prospectively determined rate. Additionally, ASCs furnish therapeutic and certain diagnostic surgical procedures, which because of their invasive nature, are not reasonably subject to over-utilization or patient abuse. The physician who requests the surgical procedure personally performs the procedure, and since medical harm would ensue to the patient if the procedure were done unnecessarily, the physician has little discretion in ordering the procedure. In addition, Medicare requires pre-certification of many surgical procedures, which prevents over-utilization.

Further, surgical services are integral to a surgeon's practice, making the ASC where the surgical procedure is furnished an extension of the surgeon's office practice. It is more economically efficient for surgeons to own jointly, rather than individually, a facility where they furnish services, and that ownership better rationalizes the costs involved and provides greater access to these services. Finally, consistent with the above, various studies, including the most comprehensive study to date conducted by the Florida Health Care Cost Containment Board, have specifically analyzed physician referral and ownership of ASCs and have found that there is <u>no problem</u> of abuse or over-utilization. The Florida legislature passed legislation, based on the Board's study, that has been a model for many other states. It expressly <u>exempts</u> ambulatory surgery services from its self-referral ban, and did so on the basis that these invasive procedures are not reasonably subject to over-utilization or abuse.

AMBIGUITIES THAT COULD IMPEDE ASCS' PARTICIPATION IN MANAGED CARE NETWORKS

As we have indicated, Stark II contains certain ambiguities that cause confusion and uncertainty within the industry, and could eliminate ASCs' participation in managed care networks. If so, this would threaten these networks' ability to provide surgical services efficiently and at the lowest possible cost.

Inpatient and Outpatient Hospital Services. The list of "designated health services" covered by the Stark II ban does not specifically include ambulatory surgical services. It does, however, include "inpatient and outpatient hospital services." This term is not defined and could be interpreted to cover any services provided by a hospital. As we understand from the legislative history and prior discussions with staff involved in drafting the provision, the ban on "inpatient and outpatient hospital services" was intended to prohibit hospitals from selling a portion of the hospital to physicians in order to "lock in" those physicians' referrals and have access to the revenue stream created by these referrals. Thus, it seems clear that the ban on "outpatient hospital services" would, for example, prohibit a hospital from selling shares of its outpatient ambulatory surgery unit to physicians. Beyond this point, because of the ambiguity of the legislation it is difficult to determine with specificity the types of arrangements involving hospital participation to which this provision may apply.

On its face, the language of the "outpatient hospital services" ban could potentially be interpreted to apply to certain arrangements that were not originally intended to be covered by the law. It could prohibit hospitals from entering into any ownership arrangement with a provider of services furnished on a hospital outpatient basis if physicians with a financial interest in the provider treat patients there. For example, "outpatient hospital services" could be interpreted to cover services furnished in a freestanding ASC that is independent from and not operated as part of any hospital, but that is jointly owned by a hospital. Under this type of arrangement, the service is physically provided and billed by the freestanding ASC, not the hospital, and the physician who requests the surgical procedure performs the procedure on his or her patient at the ASC.

Alternatively, the "outpatient hospital services" provision may apply only when various factors indicate that a hospital's involvement is so significant as to conclude that the services furnished by the hospital/free-standing provider (or ASC) joint venture actually are "outpatient hospital services." Based on prior conversations with staff responsible for drafting the provision, we believe this is a more reasonable interpretation.

Either of the foregoing interpretations are troublesome, however, in today's managed care market which depends upon the integration of health care providers to provide services efficiently and at lower costs. If hospitals and ASCs are not permitted to integrate fully, this would add an additional "layer" to the health care network. For every layer added to a network, there is a concomitant increase in cost to the entire delivery system because providers are inhibited from achieving optimum efficiencies and from equally sharing the risks. Thus, it is critical for hospitals to be integrated with independent ASCs (and other independent outpatient providers) in order to bid competitively for discounted managed care contracts, which requires the ability to provide a full array of services across a broad geographic area. For instance, the hospital may more efficiently furnish surgical services to a plan's patients if it is located on one side of town and owns an equity interest in an independent ASC that is operated on the other side of town.[1] Alternatively, the hospital could construct another facility, but that would be extremely costly and duplicative. In addition, ASCs operate at a much lower cost than the hospital's outpatient surgical department. Various studies have found that list charges for outpatient surgery are 25 percent to 40 percent lower in ASCs than in comparable hospital outpatient departments. In fact, Medicare reimburses hospital outpatient departments at a significantly higher rate than ASCs. Accordingly, it is difficult to understand why Medicare would disallow any hospital from participating in a venture that bills at the lower ASC rate when the alternative is to bill at the higher hospital outpatient department rate.

Accordingly, we request that the Subcommittee amend Stark II by specifically exempting ASCs and, in addition, by deleting or clarifying the ban on "inpatient and outpatient hospital services" to make certain that it does not apply to ambulatory surgical services.

Radiology Services. Another "designated health service" covered by Stark II is "radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services." These services have been the subject of various studies, including the Florida study, that have strongly suggested that such services are over-utilized by physician owners.

In drafting Stark II implementing regulations, we understand that the Health Care Financing Administration (HCFA) will develop a list of those services that constitute "radiology services" and

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[1] In some cases, when an ASC in which the hospital has an equity interest is on the same side of town as the hospital, ultimately the hospital closes its outpatient surgical department since the ASC provides the surgical services at a much lower cost.

thus are subject to the Stark II self-referral ban. HCFA may consider including on that list certain procedures that have as an integral part of the procedure the projection or recordation of an "image" of the body or some part thereof. We are concerned that this could thus include certain "minimally invasive" surgical services furnished by ASCs, such as laparoscopies and arthroscopies, which are surgical procedures that require the use of a video camera to visualize the relevant part of the body, i.e., the abdominal cavity and joint space, respectively.

We believe that analysis of the legislative history of Stark II and specifically, its ban on "radiology services," clearly indicates that the law is not intended to apply to these ASC services. As earlier discussed, physician ownership of ambulatory surgical services, including laparoscopies and arthroscopies, have been studied and since they have not been found to be subject to over-utilization or abuse have never been covered nor intended to be covered by Stark II. In addition, the self-referral ban on "radiology services" was recently amended by Representative Stark, the sponsor of the law, to narrow the scope of this category of services. This amendment confirms the narrow intent of the provision, and the fact that it does not thus apply to ASC procedures that use an "imaging" device, such as a video camera, as an integral part of performing the surgical procedure, particularly since these procedures are not billed as a radiology service nor are they performed by a radiologist.

Accordingly, we respectfully urge the Subcommittee to amend Stark II to clarify that the ban on "radiology services" does not apply to ambulatory surgical services.

Implementing Regulations. As you know, while Stark II has been effective since January 1, 1995, implementing regulations have not yet been drafted and likely will not be proposed or finalized for some time.[2] Even so, they may or may not provide further clarification of these foregoing matters. Accordingly, we urge the Subcommittee to delay enforcement of Stark II until final implementing regulations have been published.

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[2] Implementing regulations for "Stark I," which is applicable to clinical laboratories and which became effective January 1, 1992, have not yet been finalized.

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