Statement for the Record

of the

American College of Physicians
American Society of Internal Medicine

to the

Subcommittee on Health
Committee on Ways and Means
United States House of Representatives

RE:  Hearing on Physician Self-Referral Laws
Hearing Date:  May 13, 1999

The American College of Physicians American Society of Internal Medicine (ACPASIM), the nation’s largest medical specialty society, representing over 116,000 physicians who specialize in internal medicine and medical students, appreciates the opportunity to submit a statement for the record to the Committee on Ways and Means Subcommittee on Health on how the Stark I and Stark II physician Self-referral laws and their corresponding regulations are having a negative impact on the practice of medicine.

ACPASIM is concerned that many of the issues we raised in our comments on the Stark I final rule of August 14, 1995, and that we hoped would be clarified in the Health Care Financing Administration’s (HCFA) proposed rule of January 9, 1998, were not satisfactorily addressed. Furthermore, several new problems have arisen in this proposed rule as well. Our overall impression of the rule is that it is confusing, inconsistent, and does not reflect the current health care delivery environment. For these reasons, we have asked that HCFA rectify the concerns discussed in these comments before a final rule is published, implemented, and enforced. HCFA’s current proposal will create serious enforcement and compliance problems and generate significant unnecessary financial costs for physicians and other entities that attempt to comply, as well as for HCFA, the Department of Health and Human Services (HHS) Office of Inspector General (OIG), and the Medicare carriers. Ultimately, the proposed rule will create unintended access and quality of care problems for Medicare and Medicaid beneficiaries attempting to receive the following Stark II “designated health services:”

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

The Stark I and II self-referral legislation was enacted by Congress in response to reports that certain health care services were being “abused” by physicians with financial interests or investments in entities that provided the service(s). Congress passed legislation that prohibited physicians from referring to those entities in which they (or an immediate family member) had such an interest or investment. Congress subsequently added safeguards and revisions to Medicare and Medicaid reimbursement polices involving referral activities.

Alternative Approaches to Reducing Program Abuse

ACPASIM is pleased that Congress called the above hearing to re-examine the Stark I and II laws, given the fact that HCFA, the Office of Inspector General (OIG), and the Department of Justice (DoJ), have numerous other tools to target abusive practices. Without changes to the Stark laws themselves, any rule proposed by HCFA is likely to introduce a degree of regulatory complexity and rigidity that will interfere with legitimate arrangements between physicians and health care facilities. Other legislative and regulatory approaches can instead be used by HCFA to target abusive arrangements.

The False Claims Act (FCA), enacted over a hundred years ago, imposes civil liability on any person or entity who submits a false or fraudulent claim for payment to the United States government. The False Claims Act also allows an individual who knows about a person or entity who is submitting false claims to bring a suit, on behalf of the government, and to share in the damages recovered as a result of the suit. A person who violates the FCA must repay three times the amount of damages suffered by the government plus a mandatory civil monetary penalty (CMP) of at least $5,000 and no more than $10,000 per claim.

The Anti-kickback Statute (enacted in 1972) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce the furnishing of items or services covered by Medicare or State health care programs (including Medicaid, and any State program receiving funds under titles V or XX of the Act). A CMP of up to $50,000 plus up to three times the amount of remuneration offered, paid, solicited or received could be levied for each violation of the anti-kickback provisions of title XI of the Social Security Act (as amended by the Balanced Budget Act of 1997--“BBA ‘97”).

Furthermore, in the interim between the enactment of the Stark II legislation and the publication of the Stark II proposed rule, Congress and HCFA have taken numerous steps to reduce abusive self-referral practices. The BBA ‘97, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are two major legislative efforts designed to increase and enhance the scrutiny
of providers of health care services to Medicare recipients. The BBA ‘97 increases penalties associated with fraud and abuse, revises payment to skilled nursing facilities, and improves communication with beneficiaries.

HIPAA has increased funding for Medicare program safeguards. HIPAA funding is divided between the OIG and the DoJ to coordinate federal, state and local health care law enforcement programs; conduct investigations, audits, evaluations and inspections relating to the delivery and payment of health care; help facilitate enforcement of civil, criminal and administrative statutes on health care fraud and abuse; provide guidance to the health care industry on fraudulent health care practices; and establish a national data bank to receive and report final adverse actions against health care providers.

HCFA’s contractors were also allocated additional resources to educate the provider billing community, including hospitals, physicians, home health agencies and laboratories about Medicare payment rules and fraudulent activity. This education covers current payment policy, documentation requirements and coding changes through quarterly bulletins, fraud alerts, seminars and through local medical review policy.

HIPAA also established the Medicare Integrity Program (MIP), which is intended to “promote the integrity of the Medicare program by entering into contracts” with private entities to: (1) review the activities of providers furnishing items and services reimbursable under Medicare, including medical and utilization review and fraud review; (2) audit cost reports; (3) educate providers, beneficiaries, and other persons with respect to program integrity and benefit quality assurance issues; and (4) develop and periodically update a list of items of durable medical equipment which are subject to prior authorization.

In addition, HCFA carriers have established computer claims payment edits to alert them to areas of overutilization by screening practice patterns. The National Practitioner Data Bank and the National Suppliers Clearinghouse were founded to provide information on physicians and other health care providers, including information on exclusions from plan participation due to fraudulent and abusive activities. Finally, inappropriate referrals of Medicare and Medicaid patients to outside laboratories and other designated diagnostic facilities are already prohibited under the Federal anti-kickback law.

The enhancements to the Medicare and Medicaid programs described above should help allay Congress’ original concern about physician self-referral. ACPASIM thus strongly supports Congress’ revisiting of the premises upon which the self-referral legislation was founded and comparing those premises to the current regulatory environment to determine if there still is a need for the broad regulatory provisions of this proposed rule.

A consequence of the lack of specificity in some sections of the Stark II proposed rule is that both the health care industry and federal government will have to expend tremendous resources on compliance and enforcement activities. Seeking legal counsel or OIG advisory opinions will cost physicians an enormous amount of time and money to determine if they are in compliance with this proposed rule that was intended to give physicians a “bright line” to guide their
business arrangements. Ultimately much of this effort will be wasted because the proposed rule is confusing and open to multiple conflicting interpretations. ACPASIM has obtained seven different legal briefs analyzing the proposed rule and many of the legal interpretations differ substantially. Furthermore, there is no guarantee that any of these interpretations will be the same as the OIG’s interpretation.

Should physicians and providers assume a more conservative approach in the delivery of any of the Stark II designated health services as a result of the proposed rule, the impact on patient access and the quality of health care would certainly suffer. While unnecessary overutilization should be targeted and penalties imposed, unintended underutilization is a potential consequence of the proposed rule that creates a far greater threat to Congress’ interest in assuring access and quality health care to the Medicare/Medicaid enrollees.

Issues Unresolved by the Stark II Proposed Rule

ACPASIM has previously asked HCFA to modify the proposed regulation to: (1) accommodate a shared facilities exception; (2) substitute the definition of “general supervision” for “direct supervision” in the in-office ancillary exception; (3) support Congressional legislation to eliminate the group practice compensation requirements; and (4) revise the definition of a group practice. We had hoped that the Stark II proposed rule would address these issues. The proposed rule did little to address ACPASIM’s concerns, providing no mention of shared facilities, making virtually no change in the supervision definition, expanding rather than eliminating the regulations for group compensation requirements, and adding more confusion to the group practice definition. To rectify these problems that originated with the Stark I final rule, ACPASIM urges legislative or regulatory relief to allow the four changes to the Stark II proposed self-referral rule described below.

1. Create a shared facility exemption

ACPASIM is extremely disappointed that HCFA did not create a separate shared facility exemption in the Stark I final rule, published on August 14, 1995, or in the January 9, 1998 proposed rule. We believe that creating such an exemption is within the authority of the Secretary. Furthermore, ACPASIM disagrees with HCFA’s assertion that the risk of program or patient abuse associated with a shared facilities exemption would be significant--no sufficient data to support this conclusion have yet been offered by HCFA. ACPASIM urges HCFA to reconsider its position on creating a shared facility exemption for shared laboratories and other designated health services; barring such a change, we feel a legislative remedy is clearly indicated.

ACPASIM has repeatedly called for a narrowed shared facility exception to the Stark self-referral regulations to alleviate the Stark I burden placed on thousands of physicians’ practices. Many solo practitioners want to continue to share equipment, rental space, and personnel in order to control their overhead costs while providing a necessary service to their patients. The absence of a shared facility arrangement in the Stark I regulation has disrupted physician practices. Without an exception for in-office facilities shared between two or more physicians who are not
members of a group, physicians are seemingly left with one of two options: form or become part of a group practice (which are exempted under the Stark laws); or, close their shared facilities. While the lack of a shared facility exemption in the Stark I rule adversely affected access to clinical laboratory services only, the lack of such an exception in the Stark II proposed rule places numerous other shared facilities--those that are included on the list of designated health services--at risk.

ACPASIM believes that a narrowed shared facilities exception will not violate the intent of the self-referral statute. HCFA stated in the Stark I final rule that the “in-office ancillary” exception would provide the necessary protections for sharing of certain facilities between two or more physicians who do not meet the definition of a group practice. However, ACPASIM continues to believe that a shared facility exception is necessary because the current in-office ancillary exception is not broad enough for the variety of shared facility arrangements that physicians wish to create to reduce overhead cost, while providing service to their own patients, and that do not pose any threat of patient or program abuse.

ACPASIM’s position has been supported by legislation that passed the Congress in 1995 (but was subsequently vetoed for unrelated reasons) and by the HHS Practicing Physicians Advisory Council (PPAC). ACPASIM urges that this be rectified in either a Stark II final rule from HCFA, or through legislative remedy. ACPASIM supports the following language as it appeared in the BBA’95:

A general exception from the self-referral prohibition would be established for shared in-office ancillary services that are furnished:

(I) personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician;
(ii) by a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services; and
(iii) to a patient of a shared facility physician; and
(iv) that is billed by the referring physician or a group practice of which the physician is a member.

2. Change the in-office ancillary services exception governing supervision

The Stark I final rule provided a modest exception for in-office ancillary services. A requirement of this exception was that the physician had to personally perform or “directly supervise” laboratory tests ordered under Medicare Part B. The direct supervision requirement was interpreted in the Stark I final rule to mean that the physician must be “…present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.”

ACPASIM believes that HCFA’s direct supervision requirement is unreasonable and unnecessary. Direct supervision imposes significant hardship and unrealistic demands on all
physicians with in-house shared facilities. If physicians are required to spend their days supervising the work of their technicians--trained employees whose performance is constantly evaluated--they will be hard pressed to find time to see patients and make hospital rounds. Additionally, this requirement is unnecessary because physicians already assume legal responsibility for all work performed in their shared facilities.

ACPASIM has previously asked HCFA to change the direct supervision requirement to a general supervision requirement or that HCFA adopt the more flexible definition of direct supervision contained in the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This definition states that “...the physician or group is legally responsible for the services performed by the testing personnel and for ensuring that such personnel meet licensure and certification requirements, if any, under other provisions of the law.” The physician, or person responsible for overseeing the testing in question (e.g., the lab director or general supervisor in the case of the CLIA regulations) should be available, but not necessarily on-site, when testing occurs, in case testing personnel need assistance.

The current direct supervision requirement clearly conflicts with the intent of the conferee language accompanying the Stark II Self-Referral provisions in the Omnibus Budget Reconciliation Act of 1993, which specified that: "The conferees intend that the requirement for direct supervision by a physician would be met if the lab is in a physician's office which is personally supervised by a lab director, or a physician, even if the physician is not always on site." (emphasis added).

The Stark II proposed rule does not provide any changes in the direct supervision definition in the manner requested by ACPASIM. It does, however, provide for short, emergency and routine absences by the physician. The appropriate length of these absences is left to the carriers to determine on an individual basis. This modest change in the definition of general supervision is inadequate. ACPASIM has urged HCFA to replace "direct supervision" with "general supervision" in the in-office ancillary services exception language in the Stark II final rule. If HCFA decides instead to maintain a "direct supervision" requirement, then we would seek legislative relief for a change in the definition as follows:

the physician or group is legally responsible for the services performed by non-physician personnel and for ensuring that such personnel meet licensure and certification requirements, if any, applicable under other provisions of the law. Direct supervision does not require that physicians be physically present when an item or service is provided.

This definition would allow physicians to perform all of their professional duties while continuing to be personally responsible for the services provided by the laboratory personnel.

We are greatly troubled that after directly quoting language from the conferees' report, HCFA went to great length to explain why Congress did not really intend to allow the physician to be at an alternative site when the tests are being performed. The conferees' report is unambiguous;
Congress clearly intended for the direct supervision requirement to be met "even if the physician is not always on site."

3. **Eliminate the prohibition on referrals based on compensation arrangements**

The Stark II proposed rule retains a prohibition on certain compensation arrangements and contains a number of new provisions that address how a group practice must distribute group costs and revenues. Group practices are required to have a method of distributing costs and revenue that has been “previously determined.” Group practice payments to individual group members may not be made on the basis of the value or volume of that individual member’s referrals. The Stark II proposed rule does not allow for the distribution of profits that belong to a particular specialty or subspecialty because of concern that such specialty profit pools could result in payments for referrals. A physician in a group practice may be paid a share of the overall profits of the group, or a productivity bonus based on services personally performed or services “incident-to” the personally performed services.

Physicians in a group practice should be allowed to devise their compensation arrangements without unnecessary government intrusion into their business practices. The ability to structure compensation arrangements within a group by taking into account varying services at different sites, along with associated differences in expense structure, is vital to anybusiness. The group practice compensation requirement, as retained and expanded in the Stark II proposed rule, represents an onerous and unnecessary intrusion into the internal affairs of physician practices, and is impossible to implement in a fair and equitable manner.

As a practical matter, it is impossible for group practices to redistribute income from ancillary services without at least indirectly taking into account the volume or value of the referrals made by the physicians within that group. The ambiguous language of the Stark II proposed rule, however, will cause group practices to question whether the distinctions, no matter how well drawn, are appropriate. ACPASIM urges HCFA to provide clear, bright-line standards if the group compensation requirements are retained in the final rule.

Finally, these prohibitions force physicians to arrange their financial affairs differently for the Stark II designated health services than for all other health services they provide (which may include the designated health services for non-Medicare/Medicaid patients). This will increase the administrative burden and costs to comply for physicians, and could lead to problems of patient access should physicians become overly conservative in their practice patterns as a result of the proposed rule’s interpretations of group compensation arrangements. ACPASIM seeks elimination of as much of the group practice compensation arrangement prohibitions from the proposed regulation as is allowed under the current law and would support a legislative repeal of this entire portion of the Stark law.

4. **Revise the definition of a group practice**

The definition of “group practice” is critical to compliance with the Stark in-office ancillary exceptions. Unfortunately, the Stark I final regulation poorly defined membership in a group
practice. Although most group practices consider only those who are owners and/or employees of the practice as a group member, the Stark I final regulation included all independent contractors, regardless of the amount of time that they spent at the practice, as members of a group practice. Consequently, many group practices would have difficulty meeting HCFA’s regulation that “substantially all” of the services provided by the group be done so by members of that group practice.

The Stark II proposed rule now appropriately excludes independent contractors from the definition of group membership. However, the revised definition now creates a new problem--it also proposes to no longer allow independent contractors to supervise the provision of designated health services under the in-office ancillary services exception. ACPASIM has asked HCFA to revise this definition in the Stark II final rule to allow independent contractors to supervise the provision of designated health services under the in-office ancillary services exception--but continue to not count the independent contractors as true members of the group under the patient-care “substantially all” requirement. If HCFA is unwilling to make this change, then we would ask that it be effected with a legislative change by Congress.

New Problems Created by the Stark II Proposed Rule

The Stark II proposed rule creates several new problems that will be a detriment to patient access to timely medical care. ACPASIM has previously asked HCFA to make the following four changes to the Stark II proposed self-referral rule described in detail below to rectify these new problems with the proposed regulation: (1) reduce the number of Stark II prohibited designated services (under the authority given the Secretary to exempt services that do not pose a risk of program or patient abuse); (2) do not include prescription drugs administered in the physician’s office as “outpatient prescription drugs;” (3) create an exception for durable medical equipment provided in the physician office; and (4) eliminate the group practice attestation requirements. If HCFA is unwilling to make these changes, then we would ask that Congress implement them through legislative changes.

1. **Reduce the number of Stark II prohibited designated services**

A number of services covered by the Stark II prohibition have not been associated with Medicare program abuse, and offer little or no opportunity for overutilization. ACPASIM believes that their inclusion on the list of designated services is disruptive and interferes with patient access to care, producing the unintended consequence of underutilization. We thus urge that the list of designated health services be reduced, thereby increasing access to care. We would specifically recommend that all services from the designated health services list be exempted, with the exception of clinical laboratory services, radiology, physical therapy, and occupational therapy.

2. **Do not include prescription drugs administered in the physician’s office as “outpatient prescription drugs”**

The above recommendation asked HCFA to reduce all Stark II designated services to lab, radiology, physical and occupational therapy. If this were not administratively or legislatively
possible, ACPASIM would request the exclusion of drugs administered in the physician’s office from HCFA’s current definition of outpatient prescription drugs and to create an exception for durable medical equipment (DME) provided in the physician’s office (described in recommendation 3 below) as well.

The Stark II proposed rule defines outpatient prescription drugs as “those drugs (including biologicals) that a patient can obtain from a pharmacy with a prescription (even if patients can only receive the drug under medical supervision), and that are furnished to an individual under Medicare Part B.” Erythropoietin (EPO) and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility are excluded.

Without further instruction from Congress on what constitutes “outpatient prescription drugs," HCFA has assumed that Congress intended to include only drugs furnished to individuals under the Medicare Part B benefit and to exclude drugs furnished by providers under Medicare Part A. HCFA’s definition includes a variety of prescription drugs given in the physician’s office which are administered during the patient’s visit. Such drugs would include treatments for cancer, antibiotics, renal therapy, and vaccines. Prohibiting the prescription of such drugs in the physician’s office would clearly create serious patient access problems.

3. Create an exception for durable medical equipment provided in the physician office

Similar to our concerns regarding outpatient prescription drugs delivered to the patient in the physician office, the January 9, 1998 proposed rule prohibits the delivery of DME, which are integral to the practice of office-based medicine. Without the ability of physicians to provide these essential therapeutic services, patient care will suffer as access to care is delayed. These in-office services have not been associated with program abuse and offer little or no opportunity for overutilization. The inclusion of these services on the designated services list is disruptive and interferes with patient access to care, producing the unintended consequence of underutilization. ACPASIM’s position has been supported in the 1995 Balanced Budget Conference Agreement, the 1995 “Blue Dog” Democratic budget alternative (H.R. 2530) and in President Clinton’s FY ‘97 proposed budget. Furthermore, HCFA’s inclusion of crutches as an exception under the DME in-office ancillary services proposal suggests that HCFA is aware of the problems that will be created if patients are denied access to DME in their physicians’ office.

4. Eliminate the group practice attestation requirements

ACPASIM has urged HCFA to eliminate the group practice attestation requirements contained within the proposed rule. These requirements are overly burdensome and time consuming. The administration in its 1995 "Reinventing Health Care Regulations" initiative, determined that similar physician attestation requirements to certify the accuracy of hospital diagnosis-related group (DRG) coding were cumbersome and resulted in billing delays. Consequently, HCFA eliminated the physician attestation requirement in hospitals and instead hold hospitals responsible for the accuracy of their diagnoses and procedures. The same logic should be adopted for the proposed attestation requirements for group practices.
Conclusion

The health care industry continues to be in flux, characterized by the variety of ways health care is being delivered and financed. Managed care consolidation and integration of physician practices are increasingly having an impact on accessibility and affordability of health care services, as well as methods of payment and operation. By accepting substantial financial risks, physicians in these types of arrangements have no incentive for overutilization or inappropriate referrals.

Efforts by Congress to maintain and ensure federal health care program integrity must take into account the dynamics within the health care industry that have an impact upon the delivery and quality of patient care. In developing the final rule, ASIM urges HCFA to carefully consider these and other fundamental changes in the health care marketplace.

ACP–ASIM believes that the Stark II proposed rule is confusing, does not provide appropriate relief within its regulatory jurisdiction, does not consider changes in the current health care delivery environment, and needs to be substantially revised prior to implementation. Without a comprehensive re-evaluation of the Statute and the proposed rule, serious compliance and oversight problems will be created that will likely have a negative impact on patient access to health care. We believe this type of intrusive overregulation is unnecessary given the changes that have occurred in the health care marketplace and programs recently designed and instituted within the federal health care programs to ensure the integrity of such programs.

Summary

ACP–ASIM recommends that either HCFA use its administrative authority to take the following actions in implementing the final Stark II rule, or that Congress assure these measures are effected legislatively should HCFA choose not to do so:

1. create a shared facilities exception;
2. substitute the definition of “general supervision” for “direct supervision” in the in-office ancillary exception;
3. to the extent permissible under current law, eliminate the prohibition on referrals based on compensation arrangements;
4. revise the definition of a group practice to allow independent contractors to provide supervision of designated health services requiring direct supervision to meet the in-office ancillary exception;
5. reduce the number of Stark II prohibited designated services under the Secretary’s authority to exempt services that do not pose a significant risk of program or patient abuse
6. do not include prescription drugs administered in the physician’s office as “outpatient prescription drugs;”
7. create an exception for durable medical equipment provided in the physician office; and
8. eliminate the group practice attestation requirements.
ACPASIM appreciates the opportunity to comment on the Stark II proposed rule. We are prepared to work with Congress and the Administration to develop legislation which would identify and address inappropriate referrals and overutilization of Medicare and Medicaid services, while allowing for innovation in the health care marketplace.