April 30, 2001

Michael McMullan, Acting Administrator  
Health Care Financing Administration  
Department of Health and Human Services  
Attn: HCFA—1809—FC  
P.O. Box 8013  
Baltimore, Maryland 21244—8013

RE: Medicare and Medicaid Programs; Physicians’ Referral to Health Care Entities With Which They Have Financial Relationships  
(Federal Register, Vol. 66, No. 3, Thursday, January 4, 2001)

Dear Acting Administrator McMullan:

The American College of Physicians–American Society of Internal Medicine (ACP–ASIM), representing over 115,000 physicians who specialize in internal medicine and medical students, is pleased to offer its comments on the Health Care Financing Administration’s (HCFA) Phase I final rule on “Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships” as published in the Federal Register, Volume 66, No. 3, on January 4, 2001.

In general, we are pleased with HCFA’s effort to address many of the concerns raised in our proposed rule comments dated May 11, 1998. The final rule represents a substantial improvement over the proposed rule, smoothing the delivery of patient care through the removal of barriers to many common types of referral and financial arrangements that exist among physician practices and other entities. These welcome improvements include: excluding services personally performed by the referring physician from the definition of “referral”; no longer requiring a referring physician’s presence to meet the supervision requirement needed to qualify for the in-office ancillary exception; making it easier to qualify as a group practice; allowing physicians to refer to entities with which they have a compensation relationship (as long as the compensation paid to the physician is no more than would be paid to someone who provided the same services but was not in a position to refer to the entity); allowing physicians to receive fair market value payment (on a time or unit-of-service basis) for referrals for DHS, and permitting physicians to supply patients with certain durable medical equipment (DME) required for ambulation.

Even with these improvements, the final rule remains complex, exceptionally lengthy, at times unclear, and often beyond the scope of the average physician to fully comprehend and thus comply with. Hopefully HCFA can achieve greater simplification and clarification as it responds to our comments and those of other medical associations, and in its preparation of Phase II of the final rule. We appreciate HCFA’s posting of “Physician Referral Frequently Asked Questions” on its website, and urge HCFA to expand its physician-oriented web-based training in this area as more questions are received and Phase II of the final rule is issued.
The comments which follow provide an analysis of to what degree Phase I of the final rule has addressed ACP–ASIM’s eight major recommendations contained in our May 11, 1998 proposed rule comment letter, providing updated recommendations where appropriate. This is followed by a section on “Other Concerns and Recommendations” related to the final rule.

**Recommendation 1—Create a Shared Facilities Exception.**

**Analysis of Phase I Final Rule:**

Though not specifically creating a shared facilities exception, the final rule essentially meets our objective of allowing non-affiliated physicians or groups to share a DHS facility in the same building in which they practice, such as a shared clinical laboratory. The Phase I final rule allows shared facilities as long as the physicians or different groups that share the facility routinely provide their full range of services in the same building.

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

**Analysis of Phase I Final Rule:**

This recommendation focused on the onerous in-office ancillary exception requirement that a 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.”

We feel our recommendation has been adequately addressed in the final rule by more liberally redefining the supervision requirement “as the same level of supervision that would already apply under all other Medicare payment and coverage rules for the specific service.” Also, the final rule provides practices with further flexibility in furnishing DHS, by allowing independent contractor physicians in a group practice to supervise in-office ancillary tests, something that was prohibited in the proposed rule.

**New Recommendation:** We are opposed to the requirement appearing in Section 411.355(b)(2)(B) of the final rule which states that, in order to qualify for the in-office ancillary services exception, physicians must furnish in the same building “substantial physician services that are unrelated to the furnishing of DHS payable by Medicare.” This standard is undefined and thus would leave physicians guessing as to what “substantial physician services” meant. It could also force physicians into providing services that are not vital to high quality patient care, or for which the physician has lesser expertise, just to meet a vague and somewhat arbitrary standard.
Recommendation 3—Eliminate the prohibition on paying a physician group member a share of profits or productivity bonus in a manner related directly to the volume or value of DHS referrals generated by that member.

Analysis of Phase I Final Rule:
The final rule does not eliminate this requirement, but does provide a number of useful clarifications. It makes clear that productivity bonuses may be based directly on a physician’s personal productivity, i.e., a physician may be paid a share of overall profits of the group, or a productivity bonus based on services the physician has personally performed (including services “incident to” those personally performed), provided that the share or bonus is not determined in a manner directly related to volume or value of the physician’s DHS referrals. However, physicians may not be paid any bonus based directly on their referrals of DHS that are performed by someone else within the group, unless those services are provided “incident to” the physician’s personally performed services. In addition, the “incident to” services must be directly supervised by the physician.

The final rule is helpful in providing a definition of “overall profits” as “either the group’s entire profits from Medicare payable DHS, or the profits derived from the Medicare payable DHS of any component of the group practice that consists of at least 5 physicians.” Unlike the proposed rule, the final rule also offers useful guidance to group practices in setting out a number of distribution methods for overall profit shares and productivity bonuses which “will be deemed not to relate directly to the volume or value of referrals.” The final rule also offers groups the flexibility to utilize any other distribution method as long as the methodology is reasonable and verifiable and not directly related to the volume or value of the physician’s referrals of DHS.

Recommendation 4—Revise the definition of group practice.
ACP–ASIM is generally pleased with the final rule’s less restrictive definition of group practice, which should provide helpful opportunities for sheltering group practice/in-office ancillary arrangements from the Stark Law’s purview. In particular, we appreciate the final rule’s inclusion of two of our specific recommendations: (1) allowing independent contractors to supervise the provision of designated health services under the in-office ancillary services exception; and (2) not counting the independent contractors as true members of the group, in order to help groups meet the requirement that “substantially all” group practice members’ services be provided through the group. Relative to the latter, we also appreciate the final rule’s more liberal gauges for measuring a physician’s “patient care services,” also helpful in meeting the “substantially all” standard.

New Recommendation:  ACP–ASIM acknowledges that HCFA attempted in Section 411.352(d)(5) to give 12 months of lead time to new physician practices that would allow them to qualify as group practices without requiring that “at least 75% of the total patient care services of the group practice members . . . must be furnished through the group and billed under a billing number . . .” However, the final rule states that this exception would not apply to an “existing group practice (that) admits a new member. . .” This application of the 75% rule to new physicians joining an existing practice could result in many group practices losing their group practice designation for the period of time when a new physician joins the practice, and
several months thereafter. It would be a substantial disincentive for physicians wishing to bring younger physicians into their practice. In addition, many physicians are not able to obtain Medicare billing numbers for up to their first nine months of practice, since the carriers have not been able to process their Medicare enrollment applications to permit submission of claims. Thus, a new physician often would be precluded from contributing revenues to the group practice until the physician’s enrollment application has been accepted. This result is not supported by the goal of the statute or any public policy goal.

As such, ACP–ASIM recommends that new physicians’ services should not be included in the group practice pool for purposes of the 75% rule calculation. One possible approach would be to deem new physicians joining an existing group practice as “physicians in the group” for the first twelve months that they join a practice, and then as a “member of the group practice” after that time. This interim designation would still require the existing group practice to conform to the 75% rule, while allowing the group practice to hire physicians without being unreasonably penalized under the self-referral statute.

We also strongly urge HCFA to modify its requirement that a solo practitioner employ at least one other full-time physician to qualify as a group practice, so that a physician employing a part-time physician would also be able to qualify for the designation. Without meeting the definition of a group practice, the part-time physician would not be permitted to supervise employees under the in-office ancillary exception. Physicians with these types of part-time arrangements are considered to have group practices within their communities, and we strongly support the modification of this language to incorporate the reality of many physician practices.

**Recommendation 5--Reduce the number of Stark II prohibited designated health services.**

**Analysis of Phase I Final Rule:**
The source of this recommendation was the fact that 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. The final rule has largely addressed this recommendation by:

- Linking the definition of certain DHS (clinical laboratory, physical therapy, occupational therapy, radiology and certain imaging, and radiation therapy services) to specific CPT or HCFA HCPCS codes for those services (codes to be updated annually).
- Excluding from the applicable DHS definition those services that would otherwise constitute a DHS, when they are provided as part of a bundled or comprehensive payment rate (including ambulatory surgery center and skilled nursing facility Part A rates).
- Narrowing the definition of “radiology services” by excluding nuclear medicine from the definition, along with certain radiology services integral to the performance of some other medical procedure. The final rule also excludes from this definition certain radiology or imaging procedures requiring the insertion of a needle, catheter, tube, or probe (e.g., cardiac catheterization and endoscopies).

**Recommendation 6--Do not include prescription drugs administered in the physician’s office as “outpatient prescription drugs”.

**Analysis of Phase I Final Rule:**
The final rule partially addresses this recommendation by:

- Providing an in-office ancillary exception for chemotherapeutic agents and drugs administered or dispensed by a physician.
Creating a “new limited exception” for Erythropoietin and other specific dialysis drugs furnished in End Stage Renal Disease facilities.

Establishing a new exception for certain vaccines and immunizations.

New Recommendation: ACP–ASIM still maintains its original recommendation that all prescription drugs administered in the physician’s office not be classified as “outpatient prescription drugs” to avoid self-referral prohibitions.

Recommendation 7-- Create an exception for durable medical equipment provided in the physician’s office.

Analysis of Phase I Final Rule:
This recommendation has been largely satisfied in the final rule, which makes a number of durable medical equipment (DME) specific changes to the in-office ancillary services exception. DME items which physicians can dispense from their offices include:

• Aids to ambulation—canes, crutches, walkers, and folding wheelchairs.
• Blood glucose monitors.
• External ambulatory infusion pumps.

Recommendation 8-- Eliminate the group practice attestation requirements.

Analysis of Phase I Final Rule:
This recommendation has been fully adopted in the final rule. Group practices are, however, required to retain “supporting documentation verifying the method used to calculate the profit shares or productivity bonus…compensation,” and that documentation must be made available to the Secretary upon request.

Other Issues and Recommendations

1. Need for a Temporary Self-Referral Safe Harbor.
The delayed January 4, 2002 effective implementation date of the final rule, though well intended, can place physicians trying to restructure their practices to comply with the final rule in possible non-compliance with the proposed rule and subject to prosecution. This is why ACP–ASIM and 36 other medical organizations, in a letter to you dated March 21, 2001, asked that HCFA work with the Office of Inspector General to create a temporary safe harbor to protect physicians and providers from qui tam lawsuits that are filed before the January 4, 2002 final rule effective date, if they opt to restructure their practices and contracts to comply with the final rule. The safe harbor would sunset on the final rule’s effective date. We believe that a safe harbor based on the exceptions set forth in the final rule would ensure that physicians who are attempting to comply with the new standards are protected from these suits during the next several months.

2. Need for Prompt HCFA Issuance of Phase II Self-Referral Final Regulations.
We would urge HCFA to promulgate its Phase II final regulations as promptly as possible. As physicians attempt to restructure their practices and financial arrangements to conform to these new standards, they will derive more certainty from being able to view the entire self-referral regulatory landscape.

ACP–ASIM is concerned about possible interactions between the final rule and anti-kickback statute. While we agree that arrangements falling within the anti-kickback safe harbors should be protected from self-referral violation allegations, the final rule indicates physicians must be fully responsible for knowing when safe harbors do and do not apply. This interplay between the statutory requirements is exceedingly difficult for physicians and there are certain provisions in the final rule which seem to muddy the waters rather than provide clarification.

For example, the final rule indicates that hospitals may provide physicians with compliance training without violating the self-referral statute. This new exception is contrary to the Office of the Inspector General (OIG) Fraud Alert on Hospital Incentives to Physicians, which indicates that provision of compliance training may violate the anti-kickback statute. We believe that the final rule clearly encourages hospitals to offer effective compliance training to physicians practicing in the hospital. As such, and since the OIG was intimately involved in the crafting of the final rule, we recommend that the OIG revise the aforementioned Special Fraud Alert to acknowledge these changes and to allow this type of training to occur without triggering a potential kickback violation.

4. Self-Referral Exception for Communities with Demonstrated Needs

ACP–ASIM strongly urges HCFA to adopt a new exception to the Self-Referral Statute prohibition where there is a demonstrated need in the community -- for example, where there is an absence of adequate alternative facilities and/or alternative financing is not available. We recommend inclusion of a community need exception to the Self-Referral Law to allow a facility owned by referring physicians to exist in an inner-city area where there is no reasonable access in the community. This exception would be similar to the rural provider exception for ownership or investment interests in the proposed rule.

Many areas such as inner city communities and mid-size 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. A community need exception was included in The Medicare Preservation Act of 1995, which reflects that such an exception is supported by Congress.

Summary

ACP–ASIM believes Phase I of the final rule displays genuine effort by HCFA to address many of the concerns raised in our comments on the proposed rule. Yet, the final rule is massive and technically complex, still has many areas needing further clarification, and is essentially incomplete until Phase II of the final rule is issued. We thus urge HCFA to issue Phase II at its earliest convenience, to address the concerns and recommendations contained in this letter, and to launch a web-based educational program on the final self-referral rule which is tailored to a physician audience.

Please direct any questions you may have concerning this correspondence to Mark Gorden, Senior Associate for Managed Care and Regulatory Affairs, at (202) 261-4544.
Sincerely,

C. Anderson Hedberg, MD, FACP
Chair
Medical Services Committee