

February 6, 2003

Janet Rehnquist
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5246
330 Independence Ave. SW
Washington, DC 20201

Re:OIG-71 Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Inspector General:

The American Medical Association (AMA) is pleased to provide the Office of Inspector General (OIG) with comments to the Notice of Intent to Develop Regulations published in the December 9, 2002 Federal Register. The AMA believes that this solicitation of comments is a positive move in focusing attention and developing regulations on hospital credentialing based on referrals. Exclusive credentialing impacts all segments of medical practice, and the AMA believes that it warrants the OIG's serious consideration and official guidance. Exclusive credentialing is a subset of economic credentialing, which evaluates economic factors completely unrelated to clinical competency. The AMA opposes the use of economic criteria unrelated to quality to determine an individual physician's qualifications for the granting or renewal of medical staff membership or privileges. (H-230.976)

BACKGROUND

The AMA has received an increasing number of reports of hospitals making credentialing decisions based upon the level of a physician's referrals to that hospital. These policies effectively prohibit a physician from referring patients to other facilities for fear of losing their medical staff membership or clinical privileges. Exclusive credentialing also stifles patient choice and interferes with the physician-patient relationship. Furthermore, this practice discounts the clinical competence, experience and quality of care provided by a physician.

The alleged rationale for these policies is to avoid "conflicts of interest" by physicians having privileges at other hospitals, or other competing entities, to ensure the "long-term viability of a hospital" or to assure "commitment" or "loyalty" to the hospital. Regardless of how they are labeled, policies or credentialing practices that exclude physicians based on the number of patient referrals are anti-competitive and should be very closely evaluated by the OIG to determine whether they violate the anti-kickback statute. A policy or practice that prohibits a physician from referring a patient to a competing hospital or facility does not differ from a policy requiring a physician to refer patients to a hospital. In these situations, clinical privileges serve as the remuneration or

thing of value that is offered to the physician by the hospital as an inducement for patient referrals.

Are Hospital Staff Privileges Remuneration?

The value of clinical privileges is found in a physician's ability to exercise those privileges to admit her/his patients, to utilize sophisticated diagnostic technology, to rely on a competent professional staff to care for the patient and to seek consultation from specialists on the hospital staff. For example, a surgeon without clinical privileges or access to the operating room is a physician without a practice or a means to make her/his living. Absent the ability to utilize clinical privileges, many physicians cannot realistically practice medicine. Courts have recognized that hospital privileges have traditionally been considered property and that physicians whose privileges are being withdrawn are entitled to due process of the law. *Foster v. Mobile County Hosp. Bd.*, 398 F.2d 227, 229 (5th Cir. 1968).

Clinical privileges are crucial to physicians. Without clinical privileges, physicians cannot admit patients to a hospital for treatment. Most, if not all, physicians cannot practice medicine effectively without the ability to admit patients to a hospital when necessary or to provide consultation when requested.

The anti-kickback statute prohibits the offering or transfer of remuneration with the intent to induce referrals for Medicare services. The OIG has defined, remuneration to include "anything of value" (see OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August, 2002). By using remuneration in the statute rather than "monetary value," Congress intended a broad interpretation, implicitly recognizing that anything "of value" may not always be monetary. Value can be monetary, or professional in nature. Clinical privileges have both a monetary value and professional value.

Clinical privileges can also represent monetary value in situations where physicians participate in managed care arrangements and are required to maintain privileges at certain hospitals in order to serve that managed care population. Without privileges, the physician cannot participate in the managed care organization (MCO). Approximately 75% of privately-insured Americans participate in MCOs. Physicians and physician groups who cannot contract with several MCOs are at a financial disadvantage and at risk for their own long-term survival. In today's health care environment, clinical privileges are essential to practice medicine. The value of clinical privileges may not be truly appreciated or understood until they are unavailable to a physician, for without privileges, physicians are often unable to practice medicine.

Exclusive credentialing policies, under any name or label, therefore, have the same effect as other forms of kickbacks that have been the subject of various OIG advisory opinions and private letter rulings issued over the past several years. As these advisory opinions have stated, if one purpose of the remuneration is to induce referrals, the law is violated. While there are limited safe harbors to protect certain types of remuneration, these safe

harbors would not apply to remuneration that is intended to prohibit physicians from referring to other facilities or from holding faculty/board positions at other organizations.

What Are the Implications of a Hospital's Denial of Privileges to a Physician who Competes with the Hospital?

Denial of clinical privileges based upon competition bases privileges purely on economic factors. The AMA believes that it limits patient choice and access to care. It also undermines physicians' professional judgment.

The primary purpose of credentialing is to evaluate the qualifications, clinical competence, experience and judgment of a physician. It is the duty of the hospital and medical staff to ensure that the physicians on staff are qualified and competent to deliver care. Since the purpose of credentialing physicians is to assure a high standard of care, the primary factor for consideration should be competency, not economic factors unrelated to quality.

Notwithstanding the demonstrated competency to obtain clinical privileges at a hospital, there are some situations where an actual conflict of interest may exist for a physician. For example, if a physician, by virtue of his or her office or position on the hospital governing board or committee, has access to the hospital's non-public financial or strategic information, then the physician may be disqualified from serving on a hospital board if she/he has a financial interest that conflicts with that of the hospital. This may also be true in regard to a physician holding board memberships on two competing hospital boards. Such conflicts, can however, be remediated without denial of clinical privileges. For example, confidentiality agreements can be required executed, and enforced.

Valid conflict of interest policies are justifiable; however, termination or denial of privileges based solely upon staff membership or affiliation with a competing hospital or participation in a competing business entity is anti-competitive and punitive. These policies are really intended to eliminate referrals to competing hospitals and other outpatient facilities that may be more convenient, cost effective, or clinically appropriate for patients.

Staff Leadership Positions and Ownership Situations

Physicians with competing, personal financial interests or similar positions at competing hospitals should not serve in positions that are privy to sensitive financial, business or strategic planning information. These situations should be addressed in conflict of interest of policies rather than by exclusive credentialing.

Employed Physicians

The implications of exclusive credentialing for employed physicians are the same as those for independent physicians. The statute can be violated with remuneration offered

to an employed physician in certain situations. For example, where a hospital owns a primary care practice and employs the physician, conditioning of privileges on referrals should raise significant issues as privileges are clearly conditioned on referral levels.

The employment status of a physician does not completely exempt exclusive credentialing from the anti-kickback law. Under the statute, there are exemptions for “amounts paid” or “payments made” to a bona fide employee in recognition of the legal relationships that may exist between professional corporations and physicians or between hospitals and physicians. For example, the salary paid to a cardiologist by a cardiology group is exempt from the statute. However, the exemptions for employees address only monetary remuneration and do not establish a blanket exemption for employed physicians.

In the context of exclusive credentialing, the remuneration is the ability to admit patients to and treat patients in that hospital (privileges). This interpretation is consistent with the HHS and OIG position that “remuneration” refers to any economic benefits such as equipment loans, rent abatements, administrative and billing services or participation in ventures offering the opportunity to generate fees.

That hospitals should not be able to require patient admissions is also consistent with the OIG’s long standing position in connection with physician recruitment incentives. In the November, 1999 anti-kickback safe harbors, the OIG exempted certain recruitment practices by hospitals as long as the recruited physician was not prohibited from maintaining privileges at another hospital and was not required to admit a proportionate share of patients to that hospital. Exclusive credentialing practices are premised on a quid pro quo of referrals to the credentialing hospital.

Contracted Physicians/Groups

Physician groups having exclusive contracts with hospitals for professional services (e.g., pathologists, radiologists, anesthesiologists) should also be able to contract with other hospitals or healthcare entities for the same services. Prohibiting a physician group from contracting with and providing services to competitors raises the same issues as with individual physicians, and conflict of interest policies should instead be applied in these situations.

Should the Exercise of Discretion by the Privilege Granting Hospital Affect the Analysis under the Anti-Kickback Statute?

Any discretion by the privilege granting hospital that considers only the referrals generated by the physician should implicate the anti kickback statute. Profitability, method of reimbursement, patient mix, market share or the physician’s impact on the hospital’s bottom line disregards clinical competence and quality patient care. When privileges are based on a promise to admit to the hospital or a promise not to admit to another hospital, then the statute should be implicated.

Hospitals should develop conflict of interest policies and enforce them consistently for all applicants and medical staff members. The policies should be clear and should focus on legitimate conflicts of interest for hospital officers, rather than termination or denial of privileges for medical staff. In addition, the volume of referrals or admissions should not be used as criteria for privileges except to the extent that a certain number of patient contacts are needed to assess a physician's competency in the usual credentialing and recredentialing cycle of the hospital.

Should Privileges ever be Conditioned on Referrals, other than the Minimum Necessary for Clinical Competency?

Privileges should never be conditioned on referrals other than the minimum necessary for clinical competency. Physician competency is measured by clinical performance and skills. The AMA acknowledges that hospitals must have clinical data available to evaluate physicians, and that a minimum number of contacts or admissions is necessary to provide that data. The AMA also recognizes that utilization of hospital resources can be used as a measure for clinical performance and skills. The medical staff has a responsibility to address these issues through quality improvement initiatives or disciplinary action as provided in the bylaws.

Establishment of an overall minimum number of inpatient admissions or outpatient encounters may be valid. However, an "all admissions" requirement while serving the economic interests of the hospital may not be in the best interest of providing quality care to patients. Privilege decisions based purely on economic factors, unrelated to quality care, cannot be seen as anything other than excluding physicians who choose not refer patients to that hospital.

What is the Effect of Credentialing Restrictions that Apply to Only Members of a Group Practice?

A hospital's determination that a conflict of interest exists should apply solely to the affected physician rather than to that physician's group practice. While there may be a concern of confidentiality between a group member who has a hospital board role and other members of the group, confidentiality agreements can address these issues and, in fact, are often used by hospitals for board members and others who are privy to confidential and proprietary information.

The AMA very much appreciates the opportunity to submit comments on exclusive credentialing. This is a problem that afflicts many communities, and that has the potential to significantly limit patient choice of physicians and facilities. We urge the OIG to formulate regulations that would prevent hospitals from conditioning privileges on referral levels or upon an agreement not to seek medical staff privileges or admit patients to other hospitals.

Sincerely,

Michael D. Maves, MD, MBA