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VIA U.S. EXPRESS MAIL

February 4, 2003

Officer of Inspector General
Department of Health and Human Services
Attention: OIG-71-N
Room 5246
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Response to OIG Solicitation of Public Comments on December 9, 2002

To Whom It May Concern:

The law firm of Horty, Springer & Mattern, P.C. devotes its practice exclusively to hospital and health care law. We advise hospitals and their medical staff leadership all over the country, with an emphasis on hospital-physician relationships, especially concerning credentialing and peer review activities.

We would like to submit the following in response to the solicitation of public comments regarding the development of possible guidance addressing certain credentialing practices that appeared in the December 9, 2002 edition of the Federal Register (67 Fed. Reg. 72894). In filing this comment letter, we are not acting on behalf of any client, but rather are relying on our experience of over 30 years in this field. The solicitation was

prompted by a request from the American Medical Association ("AMA") to issue guidance regarding the legality, under the Antikickback Statute, of certain practices in connection with the granting of "hospital privileges."

If the positions advanced by the AMA are adopted by the OIG, it will have a profound negative effect on the ability of hospitals to conduct effective and meaningful credentialing and peer review and to properly serve their communities. It will also make it more difficult to address patient safety concerns in the hospital. It will also fly in the face of decades of legal precedent holding that courts and administrative agencies must give deference to policy decisions by hospital boards establishing qualifications for physicians who seek to practice at the hospital. The corporate responsibility and liability of hospitals for the care and safety of patients is crystal clear in the law.

The solicitation sought public comment on three questions: (1) Are hospital staff privileges "remuneration"? (2) What are the implications of a hospital's denial of privileges to a physician who competes with the hospital? and (3) Should the exercise of discretion by the privilege-granting hospital affect the analysis under the Antikickback Statute? Each of these questions will be addressed in turn. But first it would be helpful to briefly review the status and purpose of the hospital medical staff and the nature of the relationship between the hospital and individual practitioners who are granted medical staff appointment and/or clinical privileges.

The hospital medical staff had its origins in the "Minimum Standards for Hospitals" developed by the American College of Surgeons ("ACS") in 1918. These standards were adopted in response to a report commissioned by the ACS that was highly critical of medical care rendered in hospitals at that time. According to the ACS Standards, physicians and surgeons in hospitals should be organized into a "definite medical staff" which was defined as "the group of doctors who practice in the hospital...." The purpose of the medical staff was to: "(a) initiate and, with governing board approval, adopt rules, regulations, and policies governing professional work of the hospital; and (b) review and analyze at regular intervals their clinical experience."

The medical staff is legally a division of the hospital, having been created by and remaining ultimately accountable to the hospital governing board. Exeter Hospital Medical Staff v. Board of Trustees of Exeter Hospital, 810 A.2d 53 (NH 2002); c.f., Opinion of AMA Council on Ethical and Judicial Affairs E-4.05 (hereinafter referred to as "AMA Opinions"). The medical staff has the responsibility to perform essential

functions on behalf of the hospital in accordance with licensure laws and accreditation requirements. AMA Opinion E-4.04. The Medicare Conditions of Participation for Hospitals ("COPs") require that the medical staff be accountable to the governing body for the safety and quality of the medical care provided to patients. 42 C.F.R. §482.22(b).

While the medical staff is accountable to the board for safety and quality, the COPs (as well as state licensure laws) place the legal responsibility to operate the hospital and to appoint physicians to the medical staff on the board precisely for safety reasons. Specifically, 42 C.F.R. §482.12(a) states:

> Standard: Medical staff. The governing body must: (1) *Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;* (2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff; (3) Assure that the medical staff has bylaws; (4) Approve medical staff bylaws and other medical staff rules and regulations; (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients; (6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and (7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society. (Emphasis added.)

Subsection 1 establishes that hospitals participating in the Medicare program have discretion to determine that physicians who have financial relationships with competing facilities or services are not "eligible candidates for appointment to the medical staff."

Physicians and other practitioners who wish to treat patients at a hospital must apply for and be granted medical staff "appointment" (which means that the board has determined that the applicant has met the basic qualifications for appointment to the medical staff) as well as "clinical privileges" (which means that the board has determined that the physician can competently and safely perform specific procedures within his or her speciality area). The process by which hospitals determine whether physicians are qualified for medical staff appointment and clinical privileges is usually referred to as "credentialing," and medical staff appointment and clinical privileges, although distinct, are sometimes referred to generically as "hospital privileges." See 42 U.S.C. §11151(3).

There is no constitutional right to be appointed to a medical staff, even in a public hospital. Hayman v. City of Galveston, 273 U.S. 414 (1927). In cases where physicians have challenged hospital actions denying or revoking their medical staff appointment and clinical privileges, courts have accorded great deference to the hospital board. This principle has been so long and well established that it needs almost no support, but the oft-cited case of Sosa v. Board of Managers of the Val Verde Memorial Hospital, 437 F.2d 173, 177 (5th Cir. 1971) sums it up:

> No court should substitute its evaluation of such matters for that of the Hospital Board. It is the Board, not the court, which is charged with the responsibility for providing a competent staff of doctors....Human lives are at stake, and the governing Board must be given discretion in its selection so that it can have confidence in the competence *and moral commitment* of its staff. (Emphasis added.)

In Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic, 65 F.3d 1406 (7th Cir. 1995), Judge Posner concluded that this discretion would extend to decisions that would render ineligible for appointment physicians with affiliations that conflict with the hospital's strategic objectives. The plaintiff in that case, CompCare HMO, argued that hospitals whose medical staffs were "controlled" by physicians affiliated with the competing Marshfield Clinic improperly "restricted staff privileges at those hospitals of independent physicians." The court concluded:

> Hospitals are not public utilities, required to grant staff privileges to anyone with a medical license. The Marshfield Clinic's reputation for high quality implies selectivity in the granting of staff privileges at hospitals affiliated with the Clinic. Physicians employed by the Clinic, which has its own HMO, are hardly to be expected to steer their patients to another HMO, as they would be doing if they used their control of hospital staffs to induce the hospital to join another HMO. And given the extensive network constituted by the physicians either employed by or contracting with the Clinic, they would have little occasion to 'cross-cover' with other physicians and would be reluctant to do so if, as is completely consistent with CompCare's version of the 'essential facilities' doctrine, the Clinic maintains a reputation for high quality by being selective about the physicians to whom it entrusts its customers.

With this background, we offer our observations on the three questions posed by the OIG's solicitation of public comments.

1. Are Hospital Staff Privileges "Remuneration"?

The OIG has traditionally taken a broad view of what constitutes "remuneration" as that term is used in the Antikickback Statute. As the OIG observed in the Preamble to the 1991 safe harbor regulations, 56 Fed. Reg. 35952 (July 29, 1991):

> Congress's intent in placing the term "remuneration" in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever. The statute's language makes clear that illegal payments are prohibited beyond merely "bribes," "kickbacks," and "rebates," which were the three terms used in the original 1972 statute. The language "directly or indirectly, overtly or covertly, in cash or in kind" makes clear that the form or manner of the payment includes indirect, covert, and in kind transactions. Moreover, the statutory exception for discounts demonstrates that Congress prohibited transactions where there is no direct payment at all from the party receiving the referrals.
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> The statute's legislative history supports this reading of the term "remuneration," and makes clear that the fundamental analysis required of a trier of fact is "to recognize that *the substance rather than simply the form of a transaction should be controlling*." 123 Cong. Rec. 30,280 (1977), Statement of Chairman of the House Committee on Ways and Means and principal author of H.R. 3, Representative Rostenkowski. (Emphasis added.)

House Report No. 95-393(II), which accompanied the Antikickback Statute, is consistent with Chairman Rostenkowski's remarks about substance prevailing over form, but also suggests that the substance of remuneration that would violate the Antikickback Statute is more in the nature of "kickbacks, bribes and rebates" which are clearly designed to influence referrals rather than value that flows to one party as an ancillary effect of an otherwise legitimate relationship with another party. Furthermore, recent OIG advisories have stated that the kind of remuneration that could trigger scrutiny of a

transaction must involve something of "monetary value" (a term that, based on a recent Westlaw search, has never to our knowledge been defined by any court) rather than psychic value. See OIG Advisory Opinion 00-03; Special Advisory Bulletin on Offering Gifts and other Inducements to Program Beneficiaries (August 2002).

Medical staff appointment and clinical privileges at a hospital unquestionably provide a benefit to physicians, since they permit the physician to use the facilities, equipment and personnel of the hospital without cost to them to treat their patients. This is a cost benefit to the patients as well. In return for this benefit, the physician assumes all the responsibilities of staff membership as set forth in the bylaws, policies, rules and regulations of the hospital and its medical staff. Courts in a number of states have recognized that the physician is contractually bound to abide by the medical staff bylaws (and the duties imposed by them) once appointed to the medical staff. E.g., Sadler v. Dimensions Health Corp., 787 A.2d 807 (Md. App. 2001); Virmani v. Presbyterian Health Services, 488 S.E.2d 284 (N.C. App. 1997); Giannetti v. Norwalk Hospital, 557 A.2d 1249 (Conn. 1989). These duties may include, in addition to the basic duty of providing competent care to patients in an ethical and non-disruptive manner, participation in medical staff activities on behalf of the hospital such as serving on peer review committees, providing coverage for the emergency room, and assisting in the training of medical students and residents. Far from being "remuneration" unilaterally conferred by the hospital, any value conferred on a physician by virtue of appointment to a hospital medical staff is part of a "two-way street" of corresponding obligations owed back to the hospital -- obligations that go directly to the hospital's cooperate responsibility to its patients. The benefits of medical staff appointment are not extended to physicians without any corresponding obligations, and certainly not for the purpose of inducing the physician to refer to the hospital.

Likewise, it is difficult to see how medical staff appointment can be said to confer "monetary value" on a physician. Medical staff appointment and clinical privileges are not transferrable and therefore have no independent monetary value to the physician. Herbert v. Newton Memorial Hospital, 933 F. Supp. 1222 (D.N.J. 1996) *aff'd* 116 F.3d 468 (3d Cir. 1997). Prior statements from the OIG have indicated that free goods or services provided to a physician must have "independent value" to the physician in order to be considered remuneration that could violate the anti-kickback statute. Advisory letters dated July 3, 1997 (re: free computers and fax machines); August 4, 1997 (re: free biopsy needles); and October 2, 1997 (re: free services from clinical labs).

Furthermore, while a physician can bill for professional services performed in the hospital, he or she cannot bill for the "technical" services performed by the hospital itself. It is also unethical for a physician to bill a patient for securing admission to a hospital, something that the physician could only do if he or she were appointed to the medical staff. AMA Opinion 4.01. Any benefit to physicians is incidental to the purpose of the Hospital to serve its patients. Therefore, medical staff appointment and clinical privileges do not confer the kind of "monetary value" or "remuneration" on physicians of the sort that would trigger scrutiny under the Antikickback Statute.

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

Even if medical staff appointment or clinical privileges did constitute remuneration, it would be incorrect to conclude that a hospital could not refuse to grant appointment and privileges to a physician with a financial relationship with a competing facility.[1] To do so would create an entitlement on the part of physicians with competing financial relationships that would fly in the face of a long history of judicial and administrative rulings.

As the OIG has often stated: "Remuneration for referrals is illegal because it can distort medical decision-making, cause overutilization of services or supplies, increase costs to Federal health care programs, and result in unfair competition by shutting out competitors who are unwilling to pay for referrals. Remuneration for referrals can also affect the quality of patient care by encouraging physicians to order services or supplies based on profit rather than the patients best medical interests." OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59440

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[1] For the purpose of discussion, we are using the term "financial relationship" in the same general sense that it is used in the Stark Law, i.e., an ownership or investment interest or compensation arrangement. Such a financial relationship would not include a situation where a physician merely had privileges to treat patients at or otherwise refer patients to another facility. Thus, the kind of policies described below would not affect the physician's ability to practice elsewhere or prevent the physician from referring patients to the hospital's competitors. It would simply preclude the physician from being appointed to the medical staff if he or she had the kind of financial relationship with a competitor that both public policy and common sense have determined would induce the physician to refer patients to another entity instead of the hospital.

(Oct. 5, 2000). To the extent that a hospital determines that physicians who have financial interests with the hospital's competitors are ineligible for medical staff appointment and clinical privileges, the hospital's decision would be completely consistent with these objectives.

Various studies have suggested that ownership interests in facilities can distort physician decision making and result in overutilization. Mitchell and Sunshine, "Consequences of Physicians' Ownership in Health Care Facilities -- Joint Ventures in Radiation Therapy" 327 New England Journal of Medicine 1497 (1992); Kouri, Parsons and Alpert, "Physician Self-Referral for Diagnostic Imaging" 179 American Journal of Radiology 843 (2002). (Abstract and copy enclosed.) The OIG has also raised questions about the effectiveness of quality oversight of ambulatory surgery centers by state licensure and accreditation agencies. OEI Reports 01-00-00451 through 00453 (Feb. 2002). When physicians invest in single specialty hospitals, surgicenters or diagnostic facilities, they more often than not duplicate facilities and services already available at the hospital, thus increasing costs for Medicare and other payors.

Physician ownership in facilities also leads to unfair competition[2] with the hospital, based on the ability of the physician-investors to steer high paying patients to their facility while directing indigent patients and Medicaid beneficiaries to the hospital. Competition is further skewed by the fact that physician-owners of outpatient facilities tend to be less willing to shoulder their fair share of hospital medical staff duties, such as emergency room call coverage and service on peer review committees. This is not surprising since their economic interests lie elsewhere. But the effect of this trend is that hospitals are increasingly forced to compensate physicians for services that previously were obligations of staff appointment. This imposes additional costs on hospitals making it even more difficult to compete with the entities owned by the very physicians demanding payment. The hospital peer review process itself can even be corrupted when physicians with outside financial interests fail to recuse themselves when called upon to review the clinical work of their fellow investors, as the recent plea agreement in the case of U.S. v. United Community Hospital, No. 1-01-CR-238 (W.D. Mich. Jan. 8, 2003) illustrates.

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[2] The OIG has recognized that hospitals are at a disadvantage when competing with physician-owned surgery centers, and promulgated the hospital-physician joint venture ambulatory surgery center safe harbor as a partial response. 64 Fed. Reg. 63538 (Nov. 19, 1999). See also Advisory Opinion 03-02 (Jan. 21, 2003).

Finally, while there may be differences of opinion about the quality of care rendered in investor-owned versus nonprofit hospitals, most physician-owned facilities (especially outpatient facilities and services performed in the physician's office) lack the kind of rigorous peer review and quality improvement process that is second nature to full service hospitals. Therefore, if a hospital were to determine that physicians who compete with it were ineligible for medical staff appointment or clinical privileges, such an action would not only be a legal strategic decision, but also one that furthers the goals of the Antikickback Statute.

The courts have long permitted hospitals to withhold medical staff appointment and clinical privileges from otherwise qualified practitioners based on "economic" factors. In such cases, the courts have deferred to a decision of the hospital's governing board that services can be more efficiently provided in a particular manner, or that appointing every qualified practitioner would prevent the hospital from effectively carrying out its community service mission. Examples include credentialing decisions relating to exclusive contracts with a selected group of physicians, and medical staff development plans which determine the number and type of physicians that can best serve the needs of the hospital and the community. See, e.g., Hershey, "A Different Perspective on Quality" 17 American Journal of Medical Quality 242 (2002), a copy of which is enclosed.

The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") specifically contemplates that accredited hospitals may establish criteria for medical staff appointment that go beyond those related to clinical competence, including the ability to provide adequate facilities and support services to the physician and his or her patients and patient care needs for additional staff members. JCAHO Accreditation Manual for Hospitals Intent of Standard MS.5 to 5.13. The existence of a competing interest or the extent to which the physician intends to use the hospital's facilities is just one component of such criteria.

(a) Eligibility of Physicians With Competing Interests for Medical Staff Appointment

Courts have also deferred to hospital decisions that physicians who have financial relationships with facilities that compete with the hospital are ineligible for medical staff appointment and clinical privileges. In Mahan v. Avera St. Luke's, 621 N.W.2d 150 (S.D. 2001), a nonprofit hospital in Aberdeen, South Dakota adopted a medical staff

development plan that had the effect of preventing physicians affiliated with a competing surgicenter from applying for medical staff appointment. The Supreme Court of South Dakota upheld the hospital's policy and the Board's authority to adopt it. In doing so, the court specifically noted that the policy, like most hospital policies that would have the effect of denying staff appointment to competitors, was based on the Board's fiduciary obligation to do what is in the best interest of the community:

> When making these decisions, the Board specifically determined that the staff closures were in the Aberdeen community's best interests, and were necessary to insure 24-hour neurosurgical coverage for the Aberdeen area. By preserving the profitable neurosurgical services at ASL [the hospital], the Board also insured that other unprofitable services would continue to be offered in the Aberdeen area. ... ASL cannot continue to offer unprofitable, yet essential services including the maternity ward, emergency room, pediatrics and critical care units, without the offsetting financial benefit of more profitable areas such as neurosurgery. The Board responded to the effect that the OSS hospital [the surgicenter] would have on the economic viability of ASL's hospital and the health care needs of the entire Aberdeen community. These actions were within the power of the Board. It surely has the power to attempt to insure ASL's economic survival. As such, the courts should not interfere in the internal politics and decision making of a private, nonprofit hospital corporation when those decisions are made pursuant to its Corporate Bylaws.

Another case which supports the ability of hospitals to consider the effect of physician competition when making credentialing decisions is Williamson v. Sacred Heart Hospital of Pensacola, 1993 WL 543002 (N.D. Fla. 1993). In that case, a radiologist who was denied medical staff appointment at two Florida hospitals and membership in an IPA sued claiming that, among other things, the denials violated the antitrust laws because she was the owner of a competing free-standing diagnostic imaging center. Although the court found no evidence to support her claim that this was the reason for the hospitals' actions, the court concluded that denying appointment to a competitor would nonetheless be justified, since the plaintiff was a "very formidable competitor." According to the court:

> In light of plaintiff's position in the market, granting her any type of privileges while she still operated her own clinic would put Sacred Heart

> in the position of supporting its main competition. Essentially, Sacred Heart would be competing with itself. Faced with this possibility, it clearly had a rational, pro-competitive reason for acting independently to deny Dr. Williamson's request for privileges.

Likewise, in Rosenblum v. Tallahassee Memorial Regional Medical Center, Inc., No. 91-589 (Fla. 2d Cir. 1992), a copy of which is enclosed, a Florida trial court upheld the decision of a hospital that a heart surgeon who had a contractual commitment to a competing hospital, which caused his interests and allegiance to lie elsewhere, was ineligible for staff appointment. The court stated its reasoning as follows:

> But in the area of fair and clean competition, Dr. Rosenblum has contractual responsibilities to TCH [the competing hospital] that I think are valid considerations of TRMRC as to whether they will grant medical privileges in the field of heart surgery to the program chairman and the developer of a competing hospital. And the competition between hospitals, not only in Tallahassee but apparently on a national scale, is intense. It is real. It is not imaginary.

In the Stark regulations promulgated on January 4, 2001, HHS took the position that covenants not to compete differed significantly from a requirement to refer to a specific provider. While a hospital could not mandate that a non-employed physician refer all or a portion of his or her patients to the hospital, but the hospital could, as part of a practice purchase, prohibit the physician from competing or establishing a competing business. 66 Fed. Reg. 878-879. This rationale would also support the ability of a hospital board to establish, as a criterion to be eligible for medical staff appointment, that the physician not have a financial relationship with a competing facility.

It is therefore perfectly legitimate and not violative of the Antikickback Statute, for a hospital to adopt a policy declaring physicians who have a financial relationship with a competing facility or service to be ineligible for medical staff appointment and clinical privileges. Such a policy would not require the physician to admit any patients to the hospital or otherwise refer business there as a condition of medical staff appointment. It would simply mean that, if the physician is going to have access to the hospital's facilities, equipment and personnel, the physician must make a choice to forego a financial relationship with the hospital's competitors that would induce the physician to direct business to the competitor's facility. Such policies are not designed to exclude

physicians, but rather present the physician with a simple option -- work with the hospital in support of its mission and commitment to the community or compete.

There is no doubt that when physicians have an ownership or investment interest in a facility, they will refer patients to that facility whenever they can. This is not only intuitive but has been demonstrated empirically as well. Lynk and Longley, "The Effect of Physician-Owned Surgicenters on Hospital Outpatient Surgery" 21 Health Affairs 215 (2002), a copy of which is enclosed. Moreover, facilities which employ physicians can require their employed physicians to refer to them without violating the Antikickback Statute (which does not apply to employment relationships) or (with few exceptions) the Stark Law. 42 C.F.R. §411.354(d)(4). Therefore, requiring a physician to choose between a financial relationship with a competitor or eligibility for medical staff appointment simply levels the competitive playing field and is wholly consistent with the principles embodied in the Antikickback Statute and the Stark Law.

Nonprofit community hospitals are especially vulnerable to competition from physician-owned facilities and services. Physician-investors in competing entities have a financial incentive to divert services that still generate a financial margin for the hospital to the entities that they own. This makes it difficult for the hospital to subsidize essential community services that traditionally lose money, such as the emergency room, obstetrics, psychiatric programs and disaster preparedness. To the extent that competition from such "carve-out" entities jeopardizes the hospital's ability to fulfill its community service mission, the hospital clearly has the authority to protect its interests, as the Mahan case points out. In fact, the board of the hospital could very well be in breach of its fiduciary duty if it did nothing to respond to such a threat. Considering a policy that would deny medical staff appointment and clinical privileges to competing physicians is a legitimate exercise of the board's discretion.

It is also important to consider the ethical implications of physician ownership of health care facilities in this context. AMA Opinion 8.032 makes it clear that physician investment in health care facilities should generally take place only if "there is a definite need in the community for the facility and alternative financing is not available."[3] But where a physician-owned entity directly competes with an existing hospital, it is hard

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[3] The Stark Law was an attempt to codify this AMA ethical principle. Introductory Remarks of Rep. Stark on HR 345.139 Cong. Rec. E 84-01 (Jan. 5, 1993).

to see how the physician-owned entity would be truly needed, as opposed to merely duplicating the services offered by the hospital.

The AMA has also stated that physicians have an ethical obligation to share in providing care to the indigent. AMA Opinion 9.065. To the extent that physicians invest in a facility that drains profitable services from their local hospital, physician-owned entities can hardly be said to be consistent with this duty. Thus, the effect of carve out competition on the ability of physicians to practice in an ethical manner provides an additional basis for a board policy regarding physician competition.

(b) Volume Requirements

Hospitals have long required that physicians perform a minimum number of procedures as a condition of maintaining medical staff appointment or specific clinical privileges or in order to be eligible for certain categories of staff membership. At the most basic level, there is a clear consensus that clinical proficiency in many areas is directly related to the volume of procedures that a physician performs, and minimum numbers are necessary for adequate peer review to assess safety and quality.

Therefore, hospitals routinely adopt criteria requiring that a minimum number of procedures be performed in order to qualify for certain clinical privileges, for example, open heart surgery. Hospitals also commonly require that a physician perform a minimum number of procedures at the hospital (usually 12 to 25 per year, although sometimes more) in order to be eligible for appointment to the "active" medical staff category. This status allows the physician to vote at medical staff meetings and serve on medical staff committees. It also insures that the physician will become more familiar with and thus work more effectively with the other members of the care-giving team, such as nurses and technicians. The JCAHO will evaluate the effectiveness of a hospital's credentialing program based on documented evidence that clinical privileges are not renewed if physicians do not use those privileges at the hospital. JCAHO, Intent of MS.5.12 Through MS.5.12.3. No one has ever seriously questioned the validity of limiting participation in medical staff affairs to physicians who actually use the hospital, rather than physicians who rarely if ever set foot inside the hospital's doors.

In addition, most hospitals require all physicians, except those appointed to the emeritus or courtesy categories of the staff, to perform at least some procedures at the hospital in order to be eligible for appointment of any kind. This assures that the physician will

perform a minimum number of procedures that can be meaningfully scrutinized by the hospital's peer review committees as part of the hospital's overall quality improvement program. The OIG has previously stated, in its comments regarding the physician recruitment safe harbor regulation, that minimum privilege requirements of this sort would not implicate the Antikickback Statute. 64 Fed. Reg. 63543-54 (Nov. 19, 1999).

Some hospitals have also considered requirements that a physician perform a minimum percentage of his or her practice at the hospital as a condition of medical staff appointment or for eligibility to serve on the active staff. Still others have considered policies that would require physicians to treat, in equitable proportion, the indigent, uninsured or Medicaid patients at the hospital compared to the proportion of indigent care that the physician provides at his or her office, at other hospitals or at outpatient facilities where the physician practices. The purpose of these policies is to prevent the practice of "dumping" patients with less than favorable reimbursement on the hospital. Where a physician has a financial relationship with another facility, the incentive to off-load indigent patients on the hospital, while keeping higher paying patients at his or her own facility, is increased. This not only hurts the hospital financially, it results in a back-handed subsidization of the physician-owned facility by the hospital. In the context of a nonprofit hospital, this could raise questions as to whether the physician-owned entity obtained "private benefit," which could jeopardize the hospital's tax exempt status under Internal Revenue Code Section 501(c)(3).

A hospital policy requiring a physician to perform a minimum percentage of his or her practice at the hospital would be completely in line with the hospital's community service objectives. It would also not violate the Antikickback Statute, since the hospital has not required the physician to refer any particular number of patients to the hospital. The physician would only be required to refrain from economically discriminating against certain classes of patients, or unfairly saddling the hospital with a disproportionate share of the responsibility to care for the community's indigent population.

Courts have upheld hospital policies requiring physicians to perform a certain minimum volume of procedures as a condition of medical staff appointment, holding that such requirements help maintain quality and promote patient safety. For example, in Kerth v. Hamot Health Foundation, 989 F. Supp. 691 (W.D. Pa. 1997) *aff'd* 1998-2 Trade Cas. (CCH) ¶ 72,241 (July 15, 1998), two cardiovascular surgeons filed an antitrust suit alleging a conspiracy (among a hospital, a group of cardiologists and a competing group

of cardiovascular surgeons) to destroy their practice, after they lost their privileges because they failed to perform a sufficient number of cases. The hospital had instituted a minimum volume requirement of 100, which neither surgeon could meet. Summary judgment was granted for the defendants. The volume requirement, said the court, was supported by studies linking volume and lower mortality rates. Only after the surgeons' volume dropped into the teens (during the short period in 1991-1992 during which the volume requirement was not in effect) did the hospital determine that their surgery volume had become so low that it was no longer possible to conduct a statistically meaningful evaluation of the quality of care they were providing. The court said that the hospital "was perfectly justified in requiring a minimum level of proficiency."

In Cobb County v. Prince, (Ga. 1978), the Supreme Court of Georgia rejected a physician challenge to a hospital policy requiring that if a hospital patient required a treatment, procedure, diagnostic test or other service, and the service in question was routinely offered by the hospital, then the patient would have to receive the test within the confines of the hospital. The physicians challenging the policy owned a free-standing CT scanning facility across the street from the hospital and wanted to refer patients there. In upholding the board's policy, the court said:

> The Hospital Authority's resolution requiring use of in-house facilities and services for hospitalized patients rather than permitting them to be taken from the hospital to utilize like facilities or services elsewhere is reasonable and reflects a well intentioned effort by the Authority to deal with the intricate and complex task of providing comprehensive medical services to the citizens of our state. The pre-eminent consideration in the adoption of such a resolution by the Authority was the health, welfare and safety of the patient. The Authority's resolution is a reasonable and rational administrative decision enacted in order for the Authority to carry out the legislative mandate that it provide adequate medical care in the public interest. The resolution does not invade the physician's province. Although he is required to use the facilities and equipment provided within the hospital complex for testing rather than similar facilities and equipment outside, he is nevertheless free to interpret the results of such tests and free to diagnose and prescribe treatment for all his patients.

A number of states have statutory provisions that specifically allow hospitals to base credentialing decisions on the utilization of their facilities by physicians seeking medical

staff appointment or reappointment. Ga. Code §31-7-7; Indiana Code §16-21-2-5(3)(C); Md. Health Gen. §19-319; N.C. Gen. Stat. §131E-85. Moreover, state regulatory agencies have upheld hospital policies that require physicians to perform a minimum percentage of their work at the hospital. In a September 22, 1998 letter to the President of the Pennsylvania Medical Society (copy enclosed), the Chief Counsel for the Pennsylvania Department of Health expressed an opinion that an "exclusivity" credentialing policy of a hospital did not violate the Hospital Licensing Regulations, specifically 28 Pa. Code §§107.3(c), which prohibits hospitals from denying medical staff privileges on the basis of "any...criterion lacking professional or ethical justification." The policy in question gave a "clear preference" to medical staff applicants who will perform 90% or more of their hospital clinical work at the hospital. The Department found, among other things, that the hospital had a legitimate reason for adopting the policy, i.e., maintaining its viability in the face of a market that required the hospital to differentiate itself from its competitors. Therefore, the Department concluded that the criterion "was neither unprofessional nor unethical."

3. Exercise of Discretion

Since hospitals can deny medical staff appointment and clinical privileges based on the fact that a physician has a financial conflict of interest or fails to perform a minimum number of procedures at the hospital, they should also have the discretion to apply those policies selectively in a manner determined by the governing body to be in the best interest of the community served by the hospital. To the extent that any OIG guidance suggested that discretion could not be exercised and hospitals had to adopt a "one size fits all" policy toward physician competitors, a number of unintended consequences could result.

One example of where such discretion could be legitimately exercised is in the area of community need. A hospital in a rural area could be faced with competition from a physician owned surgicenter and from an internal medicine practice that purchased equipment to perform nuclear cardiology studies on patients in its office rather than in the hospital. The hospital governing body could determine, as part of its medical staff development planning process, that there are more than enough surgeons in the area to serve the needs of the community but a shortage of primary care physicians. Under these circumstances it would be legitimate for the hospital to enforce a policy denying medical staff appointment to the surgeons who have an ownership interest in the surgicenter, but

not apply the policy against the internists, since doing so could create serious access problems in the community.

Another basis on which the governing body could legitimately exercise discretion, is the extent to which a particular competing facility or service could harm the hospital's ability to serve the community. For instance, a hospital could choose to exempt from the definition of competing financial relationships that would disqualify a physician from eligibility for medical staff appointment, ownership of basic office lab and x-ray services common in most medical practices, but apply the policy to physician offices that purchase sophisticated diagnostic equipment like nuclear cameras, MRIs or CTs.

This type of discretion could also involve the following scenario: plastic surgeons or ophthalmologists might own a surgicenter where they perform procedures for which they possess clinical privileges at the hospital but, in fact, would rarely if ever perform those procedures at the hospital due to scheduling problems or reimbursement issues. Their surgicenter would technically "compete" with the hospital because the procedures could be done at either place, but the hospital would experience little or no revenue loss as a result of this competition since the procedures would never be done there in the first place. The hospital could determine that such "competition" would not trigger a determination of ineligibility for medical staff appointment under the kind of policy described in this letter. On the other hand, if a group of orthopedic surgeons or gastroenterologists announced that they had invested in a competing surgicenter and intended to move their work out of the hospital, the hospital would likely suffer a substantial loss of revenue. Under these circumstances, the hospital board should be able to determine that the physician owners would not be eligible for medical staff appointment since they would have a financial incentive to re-direct patients/revenue away from the hospital to the facility that they own, which revenue diversion could jeopardize the hospital's continued ability to fund essential community services. Again, under such a policy, the hospital would not be requiring the physicians to refer any patients as a condition of maintaining their medical staff appointment. The physicians would simply be given a choice between their medical staff appointment and a financial relationship that would induce them to refer elsewhere.

The hospital should also have discretion to determine whether a particular level of competition might affect its relationship with a physician while others may not. For example, it would be appropriate for a hospital to decide that ownership interest in a single-specialty acute care hospital that competes with it would render a physician

ineligible for medical staff appointment, whereas ownership in an outpatient facility such as an ambulatory surgery center or independent diagnostic testing facility would not. The basis of such decision would be that a facility that competes on both an inpatient and outpatient basis would pose an across-the-board threat to the hospital's mission and thus be a materially greater challenge than one that just competed in one line of outpatient business. Likewise, a hospital should be able to determine that employees of a competing hospital cannot have clinical privileges since they may not only compete with the hospital's own employed physicians, but also seek to gain access to patients through the hospital's ER call schedule and then otherwise divert them to their employer or a facility in which they have an ownership interest.

Hospitals should have discretion to determine that certain types of financial relationships with competitors would affect a physician's relationship with the hospital in some ways but not in others. For instance, a hospital could legitimately determine that all competing financial relationships would disqualify a physician (or anyone else for that matter) from a seat on the hospital's board, since such relationships would be wholly inconsistent with a board member's fiduciary duty of loyalty to the hospital. The hospital should also be free to adopt a policy that it will not enter into a financial relationship with anyone who has a financial relationship with the hospital's competitors. The kinds of financial relationships that can be denied to competitors of the hospital include employment, medical directorships, recruitment assistance agreements and arrangements to assist with malpractice insurance premium increases or educational loan repayment. Challenges by hospital competitors to the exercise of board discretion in this area have failed in the past. Surgical Care Center of Hammond, L.C. v. Hospital Service District No. 1 of Tangipahoa Parish, 2001 WL 8586 (W.D. La. 2000), *aff'd* 309 F.3d 836 (5th Cir. 2002).

In addition to determining that financial relationships with competitors would disqualify physicians from eligibility for medical staff appointment or clinical privileges or from of the sort of relationships described in the previous paragraph, hospitals should be able to deny competitors certain prerogatives if they are appointed to the medical staff. It would be legitimate for a hospital to adopt a policy denying physicians with competing financial relationships more favorable operating room time, participation on call rotations, the ability to vote at medical staff meetings, or medical staff leadership positions. Such policies would be rationally related to the fact that a physician with such a competing interest would not fully support the hospital and thus should not be able to take advantage of everything available to other physicians. For example, physicians

with competing interests have been known to take advantage of emergency call to divert patients presenting to the hospital to their own facilities. This not only constitutes unfair competition, but could also jeopardize patient safety.

4. Consequences of OIG Guidance

If the OIG were to issue guidance suggesting that denial of medical staff appointment or clinical privileges (or other relationships with or prerogatives at the hospital) based on the fact that a physician has a financial relationship with a competitor or failed to meet minimum volume requirements violates the Antikickback Statute, a number of very serious adverse consequences would ensue. First, hospitals that relied in good faith on the very legal principles set forth above would be forced to change their policies. Physicians who were previously excluded from eligibility for staff appointment because of the hospital's policies would undoubtedly bring legal action against the hospitals or try to re-open litigation that had previously been resolved in the hospital's favor.

Moreover, any hospital decision to deny or revoke medical staff appointment or clinical privileges of physician competitors on grounds unrelated to the existence of the physician's competitive interest, such as the physician's clinical competence or professional conduct, would be challenged by the physician as a pretext to prevent competition. This tactic is often used by physician competitors who are subject to peer review, to little avail. See, e.g., Tarabishi v. McAlester Regional Hospital, 951 F.2d 1558 (10th Cir. 1991); Odom v. Fairbanks Memorial Hospital, 999 P.2d 123 (Alaska 2000). But if the OIG were to suggest that credentialing actions could violate the Antikickback Statute in certain circumstances, hospital competitors would challenge adverse credentialing actions involving them in all circumstances, creating a *de facto* entitlement on their part to medical staff appointment and clinical privileges regardless of their competence or behavior.

The net result of such a sudden and drastic change in public policy would leave hospitals at the mercy of their physician-owned competitors. Physician investors in competing facilities would be able to take advantage of being on the hospital's medical staff to gain access to patients who they would funnel to their own facilities while directing indigent patients to the hospital. The hospital would be powerless to respond to this uneven competition. In the end, the patients and the communities served by the hospital would be the ultimate losers.

We would therefore request that the OIG issue guidance clarifying that hospital decisions to exclude physicians or other practitioners who have financial relationships with competitors from eligibility for initial or continuing medical staff appointment and clinical privileges would not violate the Antikickback Statute. We would request that similar guidance be issued stating that criteria requiring practitioners to perform a minimum number of procedures or a percentage of their practice at the hospital as a condition of medical staff appointment and clinical privileges (or eligibility to serve on a certain category of the medical staff) also would not violate the Antikickback Statute, as long as such requirements are reasonably related to quality concerns or the hospital's ability to serve its community. Finally, we would request that such guidance also state that the exercise of discretion by the hospital's governing body in applying such policies or criteria would not violate the Antikickback Statute.

We hope that the OIG will find these comments useful. If you would like to discuss them further, please don't hesitate to contact me.

Sincerely,

Daniel M. Mulholland III

DMM/elm

Enclosures

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