Hospital Privileges as Kickbacks?: The Economic Credentialing Debate Commands Renewed Attention

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1. Introduction

It is universally recognized that this country’s health care delivery and financing system has undergone a fundamental restructuring in response to spiraling medical costs and the growth of the managed care industry over the last two decades.¹ By the year 2000 health care expenditures were nearly five times what they were in 1980.² At the same time, dramatic shifts in reimbursement mechanisms from the traditional fee-for-service methodology to the new managed care systems have brought enormous pressure to bear on hospitals and health systems to control costs in every facet of their operations. Due to the overwhelming leverage possessed by large commercial and governmental payers, these payers can effectively transfer the financial burdens, risks of loss, and other economic risks to hospitals.³ These market pressures are driving reform efforts and pushing hospitals to develop creative solutions to controlling health care costs.⁴

One of the outgrowths of these fundamental changes has been the development of the process known as “economic credentialing.” Broadly defined, economic credentialing refers to a situation in which a hospital credentialing decision is impacted by the broader business objectives of the hospital’s governing body. Economic credentialing has come under aggressive attack by physician trade associations such as the American Medical Association (“AMA”) and various state medical associations throughout the country. These groups argue that the process invades the realm of the credentials review process which has always been reserved to the organized medical staff, and in so doing, creates a dangerous possibility that individual quality and competence issues will be over-ridden by strictly economic concerns. However, close examination

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² National Center for Health Statistics, Health United States 2002 288 (Table 113). By the year 2000 the National health expenditure per capita has increased from $1,067.00 to $4,637.

³ Orie, supra, n. 1, at 447.

⁴ Id.
of the common forms of economic credentialing demonstrates that, in fact, quality concerns are at the heart of most economic credentialing decisions.

Despite many challenges in the courts over the last two decades by individual physicians and industry groups, the process of economic credentialing has generally been upheld.\(^5\) One of the specific legal theories that has been periodically examined and rejected over the course of many years arises under the Anti-kickback Act,\(^6\) a criminal statute designed to combat the use of direct financial incentives to induce the referral of business reimbursable through Medicare and other federal health care programs. Although this legal theory has not heretofore generated a high degree of interest as a means of regulating economic credentialing, a confluence of circumstances has now caused it to emerge to the forefront of the economic credentialing debate.

First, as a result of persistent lobbying by the AMA, the Officer of Inspector General of the Department of Health and Human Services (“OIG”), the entity responsible for interpreting and administratively enforcing the Anti-kickback Act, has agreed to undertake a review of the issue. On December 9, 2002, the OIG issued a call for comments from the hospital industry on a series of questions that have been raised internally as the OIG grapples with whether economic credentialing is a proper subject of regulation under the Anti-kickback Act.\(^7\)

The second significant factor is the emerging case law supporting the use of alleged Anti-kickback Act violations as predicates for \textit{qui tam} whistleblower suits under the civil False Claims Act (“FCA”).\(^8\) The False Claims Act provides for treble damages and substantial fines to be levied against government contractors who have defrauded the government through the submission of “false claims” for reimbursement. One of the most powerful

\(^6\) 42 U.S.C. § 1320a-7(b).
\(^8\) 31 U.S.C. § 3729 \textit{et seq.}
enforcement provisions of the FCA is the section which enables private *qui tam relators* to reap rewards of up to thirty percent of recoveries obtained on behalf of the government, plus attorneys fees. The *qui tam* industry has increasingly, since the mid-1990s, been using the Anti-kickback Act as a predicate for FCA causes of action, arguing that hospitals’ claims for reimbursement for services which have allegedly been “tainted” by Anti-kickback Act violations constitute “false claims” within the meaning of the FCA. There are significant problems with this legal theory, even as applied to traditional kickback violations. These problems are magnified exponentially when the theory is applied to the area of economic credentialing.
2. Economic Credentialing: The Policy Debate

2.1 Hospitals’ Changing Economic and Regulatory Environment

The dramatic changes in the reimbursement environment for hospitals have produced vivid analogies. One commentator characterizes the health care industry as “an enterprise caught in the violent cross winds of a tropical storm known as managed care.”\(^9\) Another asserts that “in today’s rapidly changing health care environment, hospitals have been placed in the combat zone of market crossfire.”\(^10\) Underlying the rhetoric, however, is a universal recognition that market pressures are bringing about a fundamental transformation in the healthcare industry which, among other things, has permanently altered the nature of the relationships between hospitals and their medical staffs.\(^11\)

2.2 Traditional Credentialing: The Role of the Medical Staff

A hospital’s medical staff is a self-governing body made up of all of the physicians who have privileges to treat patients at that hospital. The organized medical staff’s ultimate purpose is to ensure and further the quality of patient care.\(^12\) In furtherance of quality care, the medical staff shapes and implements admissions standards to the medical staff as well as the requirements for clinical privileges.\(^13\) Under federal law,\(^14\) state law\(^15\), and national accreditation

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\(^13\) Id.
\(^14\) 42 CFR 482.12.
\(^15\) In order to qualify for federal funds under the Hill-Burton Act, all of the states have enacted state statutes which provide minimum requirements for the credentialing process. Although the laws vary from state to state, they consistently place the primary role of assessing competence and quality of members of the medical staff in the hands of the medical staff itself. Taber and King, supra, n. 10, at 1183-84.
standards, the medical staff has the primary role, subject to the ultimate authority of the hospital’s governing body, of assessing the quality and competence of physicians for medical staff membership and privileges – i.e., credentialing. Historically, individual competence and quality were the only criteria on which these credentialing decisions were based. Therefore, hospital governing boards were quite deferential to the expertise of the medical staff in making these decisions. The changes in the healthcare industry have not altered the medical staff’s primary role in assessing individual quality and competence, but it has necessitated the governing body’s taking a more active role in credentialing decisions as a means of fulfilling its oversight obligations.

2.3 Economic Credentialing: The Role of the Governing Body

The dramatic changes in the economic framework of our healthcare delivery system have forced hospitals to adopt a more cost-oriented approach to all aspects of their operations, including the professional services rendered by physicians on their medical staffs. One outgrowth of these changes is the governing body’s increased scrutiny of broader business issues in the process of approving and denying medical staff membership and privileges – a process which has come to be known as “economic credentialing.” During the last decade, there has been a noticeable shift from the paradigm of the primary physician practicing quality health care with little concern for costs, to the primary physician as gatekeeper of efficient quality health care. This shift is reflected in applicable JCAHO accreditation standards, state law reforms, new federal legislation, and in judicial decisions. There are several specific factors

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18 Hagen, supra, n. 11, at 432.
19 Hagen, supra, n. 11 at 432-438. With regard to accreditation standards, Hagen notes that JCAHO itself has moved towards the consideration of economic factors in the credentialing process by advocating a Total Quality Management (“TQM”) approach. The TQM approach focuses not only on the quality of the health care services but also on the efficiency with which they are supplied. With regard to state law, Hagen notes that a number of states, including for example,
currently causing hospitals to place more emphasis on the economic credentialing of physicians. These include:

- An increased understanding of the physician’s influence over utilization of hospital resources and, therefore, a hospital’s economic viability;
- The introduction of competition and cost containment as simultaneous principles of public and private policy in hospital reimbursement;
- The availability of computerized databases able to capture physician-specific data; and
- Increased research into and development of medical practice guidelines.\(^{20}\)

More than ever before, hospitals are now looking to physicians to partner with them in the challenging task of controlling healthcare delivery costs in the hospital setting.

The concern for operational efficiency has traditionally been the concern of a hospital’s governing body, not its medical staff. The JCAHO accreditation manual make this dichotomy clear. Whereas the medical staff has primary responsibility for ensuring quality and competence in the delivery of medical care,\(^{21}\) the governing body has a much broader overall leadership responsibility. Specifically, the governing body has responsibility for establishing policy, maintaining quality patient care, providing for necessary resources, and providing for organizational management and planning.\(^{22}\) The California Medical Association has succinctly summarized the governing body’s oversight responsibility as follows:

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\(^{21}\) JCAHO Manual, supra, n. 16, at MS.1 (“Medical Staff.”)

\(^{22}\) JACHO Manual, supra, n. 16, at GO.2.1 (“Governance”).
Governing bodies have a fiduciary duty to effectively manage the physical and financial resources of the hospital, appoint members of the medical staff, ensure that the policies and processes are present to promote and maintain quality, provide appropriate physical resources and personnel, and ensure self-government by the medical staff with respect to the professional work performed in the hospital.  

In today’s economic and regulatory climate, the governing bodies, as they exercise this oversight responsibility, are increasingly put in the position of making business decisions which impact directly on their staff physicians’ participation on the medical staff and the exercise of their clinical privileges. “Economic credentialing” is the term which has been developed to describe situations in which a hospital board makes a credentialing decision which takes into account the economic impact of that physician’s practice on the hospital. The term has been used to refer to a wide variety of situations in which the broader business issues – particularly the need to control cost and improve efficiency – have influenced decisions regarding whether physicians are going to be granted or denied medical staff membership and privileges at a particular hospital.

Critics of economic credentialing have tended to define it in a pejorative way as being completely unrelated to quality of care issues. For instance, the American Medical Association has defined “economic credentialing” as “the use of economic criteria unrelated to quality of care or professional competence in determining a physician’s qualifications for initial or continuing hospital medical staff membership or privileges.” Likewise, the California Medical Association defines “economic credentialing” as “the use of economic criteria that do not apply to quality for granting or renewal of medical

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23 California Medical Association Board of Trustees Document #1212, “Economic Credentialing and Exclusive Contracts” (June 2000), at p. 12.
25 American Medical Association Policy Compendium 230.975, at 197, quoted in Raspanti and Laigaie, supra, n 5, at 317 (emphasis supplied).
staff membership or privileges.”

However, such narrow definitions neither accurately encompass the universe of decisions made by hospitals which take economic factors into account, nor fairly characterize the process which has come to be generally known as economic credentialing.

Most commentators who have examined the issue of economic credentialing have recognized that economic factors and quality issues are not mutually exclusive criteria, but rather, are closely intertwined in virtually every hospital decision. Many have adopted the use of the terms “hybrid” economic credentialing and “pure” economic credentialing to distinguish between situations in which quality factors admittedly come into play from those that are seen to be completely devoid of any quality analysis. However, when one examines the actual credentialing decisions themselves, it becomes apparent that

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27 Taber and King, supra, n. 10, at 1206; Raspanti and Laigaie, supra, n. 5, at 313. Raspanti and Laigaie have identified the following as examples of “hybrid credentialing” (where economic and quality issues clearly intersect):

- Malpractice experience;
- Number of hospital admissions;
- Admission diagnoses;
- Average lengths of stay;
- Inpatient resource utilization;
- Number of diagnostic tests ordered;
- Outpatient service utilization;
- Ancillary services ordered; and
- Payor mix.

They contrast that with the following examples of “pure” economic credentialing, which they assert are unrelated to quality issues:

- Whether the physician’s patient mix is beneficial (i.e., private pay, Medicare, Medicaid or charity cases);
- The size of the physician’s practice;
- Whether the hospital “needs” admissions in the physician’s practice area;
- Comparison of the reimbursements for the physician’s admissions versus other patients;
- Comparison of the number and dollar value of ancillary services used;
- Comparison of reimbursements of the physician versus alternate admission diagnosis;
- Whether the physician is admitting patients at another hospital; and
- Whether the physician has a competing economic interest (such as ownership in an ambulatory surgical center or a diagnostic center).

However, while the “pure” economic factors clearly fall further towards the economic side of the spectrum, they are rarely analyzed in isolation devoid of other considerations.
there are very few, if any instances, in which economic criteria that are considered are completely unrelated to quality concerns. Before one can characterize a credentialing decision as “hybrid” or “pure” it is necessary to look at the entire scope of issues considered in the decision-making process. We submit that quality cannot readily be divorced from economics, and that, indeed, the drive to provide quality care lies at the heart of most hospitals’ business decisions. Therefore, we believe the “hybrid” versus “pure” dichotomy is not a helpful one, since virtually all economic credentialing decisions, when viewed as a whole, fall into the “hybrid” category.

As noted above, the real distinction between traditional credentialing and economic credentialing lies in the identity and mandate of the decision-maker, rather than the specific set of criteria reviewed. Economic credentialing is a process engaged in at the level of the governing body, not the medical staff. An economic credentialing decision is one that the governing body makes to further the broader business or operational interests of the hospital, and in that context, takes into account certain economic factors not ordinarily considered by the medical staff in reviewing and acting upon medical staff credentials.

There are a whole range of credentialing decisions now being made at the board level rather than at the medical staff level. In order to better flesh out the interplay between quality issues and economic concerns, we will discuss three specific examples which typify the types of economic analysis currently being applied in hospitals today. The three examples are exclusive contracts, physician profiling and conflict of interest policies. These three approaches fall along the spectrum of the quality/economics dichotomy, with exclusive contracting often seen as falling closest to the “quality” end of the spectrum, and conflict of interest policies generally regarded as lying furthest along the path of “pure” economics.

Taber and King, supra. n. 10, at 1209 have suggested that the case of Rosenblum v. Tallahassee Memorial Regional Medical Center, No. 91-589 (Fla. Cir. 1992), which will be discussed below, presents the “pivotal” case of “pure” economic credentialing. However, as discussed below, a concern for quality was evident in the court’s discussion of the economic issues.
2.3.1 Exclusive Contracts

Exclusive contracts are generally recognized as one of the oldest and most accepted forms of economic credentialing, and have been legitimized in the courts for many years.\(^{29}\) The term refers to the decision by a hospital governing body to grant an exclusive contract to a single provider group to handle all of the hospital’s needs in a particular specialty. Such contracts are very typically awarded for the hospital-based services, such as radiology, pathology, anesthesia, and emergency medicine. Obviously, once a hospital has awarded an exclusive contract for a particular hospital department, all other applicants for privileges in that specialty area will be turned down, regardless of their individual competence and professional qualifications.

Although exclusive contracting has been called a form of “pure” economic credentialing,\(^{30}\) most courts have recognized that one of the primary reasons hospitals enter into exclusive contracts is to enhance the quality of care in the department.\(^{31}\) The New Jersey case of Belmar v. Cipolla,\(^{32}\) gives a comprehensive look at the interplay between economic and quality factors in a hospital’s decision to enter into an exclusive contract. In that case, the New Jersey Supreme Court upheld the decision by Community Hospital to grant an exclusive contract for anesthesia services. The court noted, as an initial matter, that a hospital’s responsibility is broader than simply providing a place where sick people receive treatment. It must ensure the availability of appropriate personnel and equipment needed to provide that care:

> In providing necessary treatment, a hospital must have available numerous doctors, nurses and attending staff. It must provide operating, recovery and patient rooms; as well as medicines, food, beds, and support equipment.

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\(^{29}\) Hagen, supra, n. 11, at 446-47.

\(^{30}\) Taber and King, supra, n. 10, at 1210.

\(^{31}\) Hagen, supra, n. 11, at 446-47. Hagen notes that in Dattilo v. Tucson General Hospital, 553 P.2d 700, 704 (Ariz. 1975) the court recognized that exclusive contracts enhance the quality of care, and in Redding v. St. Francis Medical Center, 255 Cal Rptr. 806, 810 (Cal App. 1989), the California court stated that the “hospital’s interest in improving patient care . . . outweighed the potential adverse economic impact on a group of doctors.”

Payment of hospital bills by third-party payors (private insurance companies or governmental agencies) requires a complicated billing and collection system. State and federal regulations add to the administrative burden. In short, a hospital is a complex business vitally affected with a public interest.33

The court then reviewed the benefits, from the hospital’s perspective, of having an exclusive anesthesia contract. They included: better use of operating room personnel, the ability to process more operative procedures, the avoidance of fee splitting between surgeon and anesthesiologist, and better 24 hour coverage.34 These cited benefits have clear quality implications, and the New Jersey high court regarded them as reasonable. The court summarized: “the evidence points to the conclusion that the decision to enter an exclusive contract for the provision of anesthesia services was motivated by the hospital’s desire to insure a high standard of medical care.”35

This case illustrates that economic credentialing is not a matter of “pure” economics: it is a function of a hospital’s decision to enter into a business relationship with a specified group of providers for the purpose of providing more efficient and higher quality care.

2.3.2 Physician Profiling

Physician profiling is another form of economic credentialing. Physician profiling is “an analytic tool that uses epidemiologic methods to compare practice patterns of providers on the dimensions of cost, service, use, or quality (process and outcome) of care.”36 Physician profiling is viewed as a powerful tool to measure the quality, utilization and cost of services provided, as well as the variations in process and outcomes of care.37 Physician profiling can

33 Id. at 537.
34 Id. at 535.
35 Id. at 539 (emphasis supplied).
37 Id.
cover a broad range of factors related both to quality and economic factors.\textsuperscript{38} Although critics have suggested that some hospitals are making credentialing decisions solely on the basis of isolated economic criteria “unrelated to quality of care . . .”\textsuperscript{39} if one looks behind the actual criteria used to understand the motivations of the hospital in using them, we submit that in most cases, there are broad quality objectives that form the underpinnings of any hospital’s use of physician profiling.

Financial data can reflect quality of care in a whole variety of ways. For instance, if a physician is over-utilizing certain diagnostic procedures (thereby subjecting patients to unnecessary risks) that trend can be observed in a review of financial data. If a physician has a very low rate of performing certain specialized procedures, that could raise an issue as to whether he or she has enough volume to maintain his or her proficiency. If a physician has an unusually high degree of readmissions to the hospital, or admissions following outpatient procedures, that can serve as a “red flag” that there may be quality of care issues that need to be evaluated. Repeated inaccuracies in billing information can also suggest office inefficiencies or ineptitude that could carry over into the clinical area. Therefore, one cannot assume that the review of financial or economic data has no significance or function in the review of an individual physician’s professional qualifications and competence.

Moreover, even financial reviews that have a more direct financial orientation – such as determining a physician’s revenue impact in a particular specialty area, or quantifying the cost of providing the surgical equipment and personnel needed to support his or her activities – can only be understood as having a broad quality objective. The hospital, through its executive team and its governing body, is charged with oversight of hospital resources and strategic planning to meet the community’s present and future needs. In order to fulfill

\textsuperscript{38} See n. 27, supra, for a listing of factors that may be evaluated in the physician profiling process.

\textsuperscript{39} Lasker, supra, n. 36 at 74 and note 18 thereto.
In short, physician profiling is a process which has a direct bearing on quality of care – both of the individual physician being profiled and of the hospital as a whole.

2.3.3 Conflict of Interest Policies

Conflict of interest policies are generally regarded as very “pure” forms of economic credentialing, i.e., credentialing decisions made on the basis of economic factors alone. Conflict of interest policies vary widely, as they are individually designed to address the unique circumstances of each hospital. A typical policy will mandate that a physician is ineligible for medical staff membership and privileges if he or she has an ownership or investment relationship with a competing facility, such as an Ambulatory Surgery Center (“ASC”), an outpatient diagnostic center, or a competing specialty hospital. Some policies go even further, and prohibit having even a compensation relationship or a medical leadership position with a competing facility. However, not all conflict of interest policies result in removal from the medical staff. Lesser potential consequence include ineligibility for medical leadership positions and ineligibility for future membership on the medical staff once the current reappointment cycle is complete.

From the physician’s perspective, conflict of interest policies are regarded as “pure” economic credentialing because the ineligibility decision is made on the basis of a single factor, unrelated to individual competence, that is seen as a direct function of the hospital’s desire to eliminate competition for services that the hospital is itself providing. On its face, the loss of privileges due to a conflict of interest can clearly be characterized as a financially-based decision. However, there often are genuine quality concerns driving the decision to adopt of conflict of interest policy. The opening of a competing
ASC across the street from a hospital by members of its medical staff can adversely impact the quality of care being delivered by the hospital in a number of ways. The hospital may lose its best physician and non-physician staff to the competing center. The hospital may lose the “best cases” (low acuity, high reimbursement, regularly scheduled cases) to the competing center, leaving it to treat difficult, high acuity cases and/or to accept “overflow” from the ASC on an unpredictable basis. All of these impacts can affect the quality of care that the Hospital can deliver, as well as increasing its costs.

Moreover, while the “cost” issue may appear purely economic, the reality is that if a hospital is experiencing increased costs and declining reimbursements over time, it will be increasingly unable to maintain the quality of its services. Quality is, at least in part, a function of the hospital’s ability to manage both its revenues and its costs.

This concept has been implicit in both of the two cases that have come closest to framing the conflict of interest question, i.e., *Rosenblum v. Tallahassee Memorial Regional Medical Center*, 40 and *Mahan v. Avera St. Luke’s Hospital.* 41 Both of these cases upheld hospital decisions excluding physicians from their medical staffs based upon the physicians’ relationship with a competing entity.

In *Rosenblum*, the Tallahassee Memorial Regional Medical Center (“TMRMC”) denied medical staff privileges to a heart surgeon who was qualified in terms of his professional qualifications and competence, but who was the founder and chairman of the heart program at a competing hospital. The court expressly ruled that the governing board was entitled to take “economic factors” into account in reaching its decision. The court discussed two different justifications for the hospital’s decision, both of which it found acceptable. The first was the concern that, if TMRMC granted privileges to the heart surgeon, it

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40 Rosenbaum v. Tallahassee Memorial Regional Medical Center, Case No. 91-589, 2nd Jud. District, Leon County, Florida, June 18, 1992.
would be required to bear the substantial cost of developing a program to support his surgical activities at the hospital. The court said:

[I]f we have a hospital with a very highly qualified physician in a rare specialty and one that is rarely used and which will be most costly to equip and he wants medical privileges extended for that purpose, then I think it is appropriate that, regardless of medical qualification, that the governing body be able to take into consideration the economic costs to establish that department. And they could deny privileges in that field because to grant them would create the concomitant requirement that the department be established, equipped and the like.42

This reason involved a mix of quality and economic factors, because the cost information the hospital considered had a direct bearing on whether the hospital was in a position to provide a quality heart program.

The second factor endorsed by the Rosenblum court was the hospital’s consideration of whether Dr. Rosenblum’s loyalty to the competing heart program, of which he was founder and chair, would impair his ability to build a successful, quality cardiac surgery program at TMRMC. Once again, the quality factor is implicit in the decision. If the hospital is not convinced of Dr. Rosenblum’s full commitment to building a good and successful program, it is predictably going to be less willing to make the capital investment necessary to support it. The board should be able to look at the “big picture” and take all the relevant factors into account.

A similar approach was taken by the South Dakota Supreme Court in the Mahan case. In that case, the hospital had decided to deny, on a prospective basis, new applications for clinical privileges in three specialty areas of orthopedic surgery. The impact of the decision was to impede an orthopedic group that had just opened a competing ASC from recruiting new surgeons.43

The orthopedic group challenged the hospital’s action, which was upheld by the state supreme court. The court’s reasoning makes it clear that,

42 Rosenblum, supra, n. 40, at 3.
43 Mahan, supra, n. 41, at 153.
once again, the economic factors were seen by the board to have a direct impact on its ability to continue providing quality care (and, specifically, adequate neurosurgical coverage) to the surrounding community. The court said that when making its decision:

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 Board also insured that the unprofitable services would continue to be offered in the Aberdeen area. When, as here, it is clear from the Corporate Bylaws that the Board has the authority to manage the corporation, that authority “would necessarily include decisions on how to operate individual departments in order to best serve the corporation’s purpose . . . The cost of such care and promotion of community health is vitally important to the community and a legitimate concern for the board. [Citation omitted]. ASL cannot continue to offer unprofitable, yet essential services including the maternity ward, emergency room, pediatric and critical care units, without the offsetting financial benefits of more profitable areas such as neurosurgery.  

Here again, it is clear that the consideration of economic and quality factors goes hand in hand. A hospital board is faced with a complex set of variables and competing needs and interests. It must be able to consider all the variables to carry out its oversight responsibility in the most effective way.

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44 Id, at 156.
3. Economic Credentialing: The Anti-kickback Challenge

For many years, the American Medical Association, the California Medical Association, and other industry groups have maintained an aggressive campaign against all forms of economic credentialing. One of the arguments which has been repeatedly raised by these industry groups is that economic credentialing may violate the fraud and abuse laws or, more specifically, the Anti-kickback Act, 42 U.S.C. § 1320a-7b. Interestingly, in 1998, the AMA acknowledged that its Office of General Counsel had analyzed the question of whether one specific form of economic credentialing, i.e., a medical staff development plan, violates the Anti-kickback Act and had determined that “it is unlikely that [such plans] implicate these laws.” This view is consistent with the opinions of many other commentators who have reviewed the broader issue of whether economic credentialing implicates the Anti-kickback Act.

Nevertheless, in 1999, the AMA formally requested the Office of Attorney General of the Department of Health and Human Services (“OIG”) to issue a fraud alert declaring economic credentialing to be a violation of the Anti-kickback Act, 42 U.S.C. § 1320a-7b(b). After the OIG failed to take action on the AMA’s request, the AMA, on November 1, 2001, passed a resolution declaring its intent to “aggressively seek resolution with the [OIG] of the issues

46 Id.
48 In 1994, Taber and King wrote that the Antikickback theory of liability would “most likely not prevail” as a means of challenging economic credentialing decisions because it: “(i) involves an overly broad interpretation of the Fraud and Abuse statute; (ii) does not pose the potential abuse sought to be corrected by the statute; and (iii) fails to account for the legal and justifiable extension of economic criteria to the overall assessment of physician competency.” Taber and King, supra, n. 10, at 1203. In 1995, Hagen concluded that “because credentialing does not focus on referrals, the likelihood of violating the statute is remote.” Hagen, supra, n. 11, at 456. Blum has commented that if the reach of the Antikickback statute is really broad enough to reach economic credentialing, then the “the very notion of utilization review, which deals in part with cost effectiveness, may not be used as a factor in credentialing decisions” – a facially absurd result. Blum believes that hospitals “should be able to develop programs using a wide range of economic measures that do not violate fraud and abuse statutes.” Blum, supra, n.17, at 70.
of the alleged fraud and abuse associated with hospital-imposed exclusivity as a form of economic credentialing." 49

The AMA’s many years of efforts have finally come to fruition. On December 9, 2002, the OIG published in the Federal Register a notice that, in response to the AMA’s request, it is soliciting comments regarding whether there are any forms of economic credentialing that raise issues under the Anti-kickback Act.50 In this section, we will review and critique the various legal theories that have been advanced in support of the position that economic credentialing violates the Anti-kickback Act, and examine the questions now being put forth by the OIG to assist it in evaluating this issue.

3.1 The Anti-kickback Act

The Anti-kickback Act is a criminal statute which makes it a felony, punishable by fines and imprisonment, to “knowingly and willfully” solicit, receive, offer or pay “any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual . . . for . . . any item or service for which payment

50 OIG, “Solicitation of New Safe Harbors and Special Fraud Alerts,” 67 Fed. Reg. 72894, at 72895 (December 9, 2002). Section III of that notice solicits comments regarding the potential fraud and abuse implications of certain economic credentialing practices. The OIG noted specifically that it had been requested by the AMA to issue guidance in this area.
may be made” under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(1)(A). The statute is drafted in extremely broad terms and, but for a series of statutory exceptions and regulatory safe harbors, could be interpreted as making it a potential crime to engage in virtually any type of business relationship that health care providers typically enter into in the ordinary course of their every day affairs. The reach of the Anti-kickback Act, however, is not limitless. It is circumscribed by at least two very important concepts relevant to this analysis.

First, in order for a violation to have occurred, there must have been a direct or indirect solicitation, receipt offer or payment of “remuneration.” Although the term “remuneration” is not specifically defined, the fact that the

51 The text of the Anti-kickback Act is as follows:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind –

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(1) and (2).

statute expressly prohibits payment of remuneration gives strong indication that what Congress had in mind was in the nature of a “payment” – i.e., either cash or a cash equivalent. The statute, legislative history, judicial interpretation and existing regulatory guidance have consistently interpreted the term “remuneration” as referring to some kind of payment. The granting or denial of medical staff privileges is not a payment. It is neither cash nor a cash equivalent. It is a grant of authority to practice one’s profession at a particular location. Therefore, the granting of medical staff privileges is not encompassed within the meaning of the “remuneration” as used in the Anti-kickback Act.

Second, the Anti-kickback Act is constrained by the concept of criminal intent. In order to violate the Act, a hospital must have engaged in prohibited conduct “knowingly and willfully.” In all the years since the Anti-kickback Act was passed, neither Congress, the courts nor any governmental agency has ever suggested that the granting of medical staff privileges could be a form of prohibited “remuneration” within the meaning of the Act, nor would it be reasonable for a hospital to conclude that the Act encompasses credentialing activities. In the absence of any such statutory or regulatory guidance, the government would be hard pressed to sustain a felony conviction against any hospital on the grounds that it had formed the requisite criminal intent to violate the Anti-kickback Act in connection with its credentialing activities.

3.2. The “Remuneration” Requirement

The Anti-kickback Act prohibits knowing and willful receipt, offer, solicitation or payment of “remuneration” in exchange for referrals. Therefore, in order for the receipt, offer, solicitation or payment of medical staff privileges to violate the Anti-kickback Act, the privileges themselves must constitute “remuneration” within the meaning of the Anti-kickback Act. The argument has been advanced that because medical staff privileges may have economic value to the physician on whom they are conferred, that they can constitute “remuneration” within the meaning of the Act. Although the argument may
have some superficial appeal, we do not believe that this position is either correct or sustainable under careful legal analysis.\textsuperscript{53}

\textbf{3.2.1. Legislative History}

The term “remuneration” is not specifically defined in the Anti-kickback Act. In the original version of the statute, enacted in 1972, the term “remuneration” did not even appear. The 1972 Act only prohibited the solicitation, receipt, offer or payment of “kickbacks, bribes or rebates” in return for referrals.\textsuperscript{54} A “kickback” is a “return of a portion of a monetary sum received, especially as a result of coercion or a secret agreement.”\textsuperscript{55} A “bribe” is “the corrupt payment, receipt, or solicitation of a private favor for official action.”\textsuperscript{56} A “rebate” is “a return of part of a payment, serving as a discount or reduction.”\textsuperscript{57} All of these terms import the specific concept of a “payoff” – i.e., the transfer of cash or a cash equivalent.

In 1997, the statute was broadened to include “any remuneration (including any kickback, bribe or rebate).” From the legislative history of the 1997 amendment it is clear that what Congress was intending to accomplish by this amendment was to enable the government to go after \textit{indirect} forms of financial payoff. The legislative history contained in House Report No. 95-393

\textsuperscript{53} In fact, it is noteworthy that even the AMA’s general counsel has endorsed the position that the mere granting of medical staff privileges does not constitute remuneration. In the 1998 AMA Board of Trustees report, the AMA noted the following: “The federal anti-kickback law makes it illegal to receive remuneration in exchange for, or to offer or pay remuneration in order to induce, the referral of Medicare or Medicaid beneficiaries. Therefore, for a medical staff development plan to be illegal under the anti-kickback law, pursuant to the plan, the hospital must give the physician “remuneration” in exchange for the referral of Medicare or Medicaid patients to the hospital. In the medical staff development plans that have been explored in this report, the only thing the hospital has extended to physicians is privileges. There are no cases on record that explore the extension of privileges in return for referrals. Moreover, the legal literature suggests that it is doubtful that the mere granting of staff privileges is remuneration within the anti-kickback statute, as a hospital does not compensate a physician for referring patients to the hospital simply by giving the physician the opportunity to admit patients.” AMA Board of Trustees report, supra, n. 45, at 5.


\textsuperscript{55} Black’s Law Dictionary, 7th Edition, p. 874 (1999). Black’s gives the following example of a “kickback:” the contractor paid the city official a 5% kickback on the government contract. The dictionary notes further that a kickback is also termed a “payoff.”

\textsuperscript{56} Id, p. 186.

\textsuperscript{57} Id, at p. 1273.
notes that the language was being extended from “kickback, bribes or rebates” to “any remuneration (including any kickback, bribe or rebate)” as a means of strengthening the statute’s ability to combat such practices as “the solicitation, offering, or acceptance of kickbacks or bribes, including rebates or a portion of fees or charges, for patient referrals.”

The House Report notes that the proposed amendments will “clarify and restructure those provisions in existing law which define the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid.” With regard to the definition of “remuneration,” the House Report states that “the bill would define the term “any remuneration” broadly to encompass kickbacks, bribes or rebates that may be made directly or indirectly, overtly or covertly, in cash or in kind.” The Report emphasizes that it does not intend to encompass payments made pursuant to legitimate employment agreements or discounting arrangements. There are, in fact, currently six express statutory exclusions to the Anti-kickback Act, all of which involve various types of financial arrangements. They include exclusions for discounting arrangements, payments made under a bona fide employment agreement, group purchasing arrangements, waiver of coinsurance for certain federally subsidized programs, and certain risk sharing arrangements.

However, the broader term “remuneration” caused immediate concern and uncertainty among health care providers as to “which commercial arrangements are legitimate, and which are proscribed.” In the words of the OIG, “concern ha[s] arisen that many relatively innocuous, or even beneficial commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.”

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59 Id (emphasis supplied).
60 Id, at 3056 (emphasis supplied).
61 42 U.S.C. § 1320a-7(b)(3)(A) – (F).
this problem, directed the Secretary of HHS to develop regulations “specifying payment practices that will not be subject to criminal prosecution” under the Anti-kickback Act.\(^{64}\) Accordingly, the OIG has promulgated four sets of “safe harbor” regulations, in 1991, 1999 and 2001, respectively, designed to give the health care industry specific guidance as to what types of financial relationships will constituted “kickbacks” within the meaning of the Act.\(^{65}\)

The OIG, in promulgating this industry guidance, has taken a very broad view of the term “remuneration.” The OIG’s commentary states that “Congress’ 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.”\(^{66}\) The breadth of this definition has necessitated the development of a wide range of regulatory “safe harbors.”\(^{67}\) It has also spawned considerable additional commentary in the form of fraud alerts and advisory opinions, all seeking to distinguish legitimate commercial arrangements from illegitimate ones. All of this regulatory guidance is directed towards various forms of cash or cash equivalents. Nowhere has it been suggested, either directly or indirectly, that the granting of medical staff privileges at a hospital would be encompassed by the term “remuneration.”

### 3.2.2 OIG Safe Harbors

In all of the regulatory guidance, the OIG consistently approaches the concept of remuneration as something involving a discrete financial payoff. The OIG speaks in terms of “business arrangements,”\(^{68}\) “business practices.”\(^{69}\)

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\(^{64}\) Id (emphasis supplied).


\(^{67}\) Id.

\(^{68}\) See, e.g., 56 Fed. Reg. at 35952 (the term “business arrangement” is used throughout the OIG’s guidance).
and “payment practices.” The OIG notes that its new safe harbors address “payment practices” which “would be prohibited by the statute but for their inclusion here.” The safe harbors themselves bear out this focus on financial arrangements that could constitute covert payoffs. The 1991 safe harbors encompass the payment of returns on investments, lease payments, payments pursuant to personal services contracts, proceeds of the sale of practices, fees charged by referrals services, payments under warranties, discounts, employment compensation, fees charged by Group Purchasing Organizations, waivers of coinsurance and deductibles, and recruitment incentives. The safe harbors added in 1999 include new recruitment incentives, obstetrical malpractice insurance subsidies, investments in group practices, cooperative hospital service organizations, ambulatory surgery centers, referral agreements for specialty services, and certain types of risk-sharing arrangements with managed care organizations. An additional safe harbor issued in 2001 involves ambulance restocking agreements.

With only one possible exception – that of cross referral arrangements - what each of these forms of remuneration have in common is that they involve...
the exchange of a discrete item of value from one person to another – i.e., “payoffs.” The cross-referral exception does present some interesting issues, which will be examined in a separate section below.

3.2.3 OIG Advisory Opinions

Likewise, the nearly ninety Advisory Opinions that have been generated by the OIG since 1997 all deal with financial transactions, payment arrangements, or the provision of free or discounted goods or services. The Advisory Opinions cover such diverse issues as discounts or waivers on co-payments and deductibles, provision of free or discounted equipment or services, provision of financial assistance or charitable donations, ownership/investment arrangements in medical facilities such as Ambulatory Surgery Centers, ambulance restocking programs, unique payment, consulting or employment arrangements, payments by vendors to group purchasing organizations, space and equipment rental agreements, recruitment incentives, special promotions or advertising, sales commissions, coordination of benefits agreements, referral services, and

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91 The OIG’s defines remuneration as the “transferring” of anything of value. The word “transfer” has a specific meaning which connotes that something of value has passed from one person to another. Black’s Law Dictionary defines the verb “transfer” as “to convey or remove from one place, person, etc. to another; pass or hand over from one to another; specifically, to change over the possession or control of (as, to transfer a title to land). To sell or give.” (Fifth Ed., 1979). Likewise, the common dictionary definition of “transfer” is “to convey from one person, place or situation to another . . . to cause to pass from one to another . . . to make over the possession or control of . . .” (Merriam-Webster’s Collegiate Dictionary, Tenth Ed., 1999). This concept is consistent with the notion of a “payoff” from one person to another.

92 E.g., Advisory Opinions Nos. 02-15, 02-08, 02-07, 01-15, 01-12, 00-5, 99-7, 99-1, 99-9, 98-6, 97-4.

93 E.g., Advisory Opinions Nos. 02-14, 02-12, 02-10, 02-6, 01-18, 01-14, 01-10, 01-11, 01-7, 01-3, 00-7, 00-3, 99-13, 99-11, 99-6, 99-2, 98-16, 98-15, 98-3, 98-2.

94 E.g., Advisory Opinions Nos. 02-13, 02-11, 02-1, 01-19, 01-9, 01-2, 00-11, 00-6, 99-10, 98-17.

95 E.g., Advisory Opinions Nos. 02-9, 01-21, 01-17, 98-19, 98-12, 97-5.

96 E.g., Advisory Opinions Nos. 02-2, 00-9, 98-14, 98-13, 98-7, 97-6.

97 E.g., Advisory Opinions Nos. 01-20, 01-16, 01-1, 00-2, 00-4, 00-1, 99-5, 99-14, 98-9, 98-4.

98 E.g., Advisory Opinions Nos. 01-8, 01-6.

99 E.g., Advisory Opinions Nos. 01-5, 98-18.

100 E.g., Advisory Opinion No. 01-4.

101 E.g., Advisory Opinions Nos. 00-10, 99-12, 99-8, 99-3.

102 E.g., Advisory Opinions Nos. 98-10, 98-1.

103 E.g., Advisory Opinions Nos. 01-13, 01-12, 98-5.
transfer of assets agreement.\textsuperscript{105} Here again, the OIG’s focus is on arrangements resulting in the transfer of cash or cash equivalents from one person to another.

3.2.4 Physician Recruitment

Furthermore, the industry guidance that does address hospital-physician relationships makes it clear that medical staff privileges have never been considered as remuneration. The most relevant guidance is the OIG’s guidance regarding physician recruitment. In 1994, the OIG issued a “Fraud Alert” on physician recruitment, identifying a list of “questionable” incentives to physicians.\textsuperscript{106} Each one of the incentives involved some form of cash or cash equivalent, e.g., cash payments, free or discounted office space, discounted billing services, free training of office staff, income guarantees, low-interest loans, payment of physicians’ travel expenses, and so forth. Nowhere in this Fraud Alert does it suggest that the granting of medical staff privileges must be separately analyzed as a “benefit” conferred on the physician -- and yet, it is implicit in the analysis, that medical staff privileges would be conferred.

In 1999, the OIG adopted a specific safe harbor for certain physician recruitment arrangements.\textsuperscript{107} To comply with this safe harbor, a Hospital must enter into a written agreement specifying the “benefits” to be conferred on the physician. The “benefits” may not be provided for more than three years. The granting of medical staff privileges is not considered a “benefit” for purposes of this section. To the contrary, it is regarded as a “condition” that the Hospital may impose on the Physician in exchange for the “benefits” conferred. (The regulations also specify that the Hospital may not, in return for the “benefits” conferred, prohibit the physician from establishing staff privileges at other facilities). If the OIG regarded the granting of medical staff privileges as a “benefit” for purposes of the Anti-kickback Act it would have had to make

\textsuperscript{104} E.g., Advisory Opinion No. 00-8.
\textsuperscript{105} E.g., Advisory Opinion Nos. 97-3, 02-3, 02-4, 97-3.
\textsuperscript{106} 59 FR 65372 (Dec. 19, 1994)
\textsuperscript{107} 42 C.F.R. 1001.952(n).
specific provision for it, if not in the safe harbors generally, then certainly in the physician recruitment safe harbor in particular.

3.2.5 Hospital-based physicians

The second area of hospital-physician relationships that has received scrutiny under the fraud and abuse laws is the area of hospital-based physicians. In fact, a 1999 OIG Management Advisory Report has been cited as supporting the proposition that medical staff privileging can give rise to violations of the Anti-kickback Act. However, in its analysis of hospital-based physician relationships, the OIG did not determine that the granting of privileges to those physicians constitutes remuneration: it actually found the reverse to be true.

The Anti-kickback Act prohibits payments in exchange for referrals. In the case of the hospital-based physicians, the OIG is concerned about situations in which the hospitals have arguably demanded payment from the physicians (in the form of capital expenditures, excessive lease payments, charitable donations, and so forth) in exchange for the facilitation of referrals to the physicians through the granting of exclusive privileges. Hospital-based services include such specialties as pathology, radiology, and emergency medicine – services which can only be performed in the hospital. Hospital-based physicians do not control their own referrals, but rather, depend on other physicians practicing in the hospital for their flow of business. Typically, hospitals will grant exclusive contracts for some or all of the hospital-based services, which provide a defined referral and income stream to the hospital-based physicians. The OIG’s concern is that if a hospital were to demand “remuneration” from the physicians in the form of excessive lease payments or charitable contributions, then the payment of such “remuneration” could be in

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exchange for the hospital’s facilitating “referrals from the other physicians on the hospital’s medical staff.”

This specific argument was made successfully in the often-cited decision in *Virginia Radiology Associate, P.C. v. Culpeper Memorial Hospital*, Virginia Radiology was a contract action in which the hospital’s radiology group challenged the legality of certain new contract terms being sought by the hospital which it alleged required it to make excessive payments to the Hospital in return for referrals. In that decision, as in the OIG Report, the granting of exclusive privileges was analyzed, not as remuneration to the physician, but as a guaranteed referral flow.

The situation presented by the current economic credentialing debate is the complete reverse of the situation presented in the case of the hospital-based physicians. The current debate is not over whether the granting of privileges facilitates referrals but whether it constitutes remuneration. It is a quantum leap from referrals to remuneration. Therefore, the literature and case-law on hospital-based physicians provides no useful guidance on this issue.

3.2.6 Privileges as a Grant of Authority

The granting of medical staff privileges does not involve payment of cash or a cash equivalent. The granting of privileges is more like the issuance of a license or permit: it is a grant of authority, not a payment. Hospitals are required by state law and industry standards to “credential” physicians as part of their overall obligation to oversee the quality and competence of the medicine provided within their walls. As noted by JCAHO, “the processes of appointment and reappointment to the medical staff and of granting or renewing or revising clinical privileges all involve using information about an applicant to

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111 OIG Report, supra, n. 109, at 4.
113 See, Melvin, supra, n. 110, at 195-97.
decide whether the individual will be *authorized to practice within the hospital* and, if so, what the individual will be *authorized to do.*

The grant of authority to practice at a particular hospital may be seen to have economic value to the physician insofar as it enables him or her to generate revenue through the treatment of patients. However, unlike bribes, kickbacks, rebates and the other forms of “remuneration” encompassed by the Anti-kickback Act, it is not intrinsically valuable. It cannot be bought, sold, or transferred by the physician to someone else. It does not generate revenue or confer value independent of any conduct by the physician. It merely permits the physician to exercise his or her profession within the walls of the granting hospital.

The only OIG discussion which equates in any way a grant of permission with “remuneration” is its Advisory Opinion No. 99-4 (March 31, 1999), in which it suggests that the transferring of a right held by one hospital district (District Two) to another hospital district (District One) to construct a medical clinic within the boundaries of District Two could constitute “remuneration” within the meaning of the Anti-kickback Act. The OIG opined that “by granting District One an opportunity to locate its clinic in District Two’s district, District Two may be bestowing on District One something of value, that is, an opportunity to generate business in District Two.” This situation, however, is not analogous to the granting of medical staff privileges, because here District Two actually has transferred a discrete right that it possessed to District One. District Two has the exclusive right (pursuant to a grant of authority by the state) to operate a medical clinic within its geographic area, and thus derive the benefit of the referral stream to that clinic. By granting permission to District One to open a clinic in its territory, it is thus relinquishing something of value – i.e., its exclusive right to the referral stream that will now go to District One’s clinic. District Two’s transfer of its right to the referral

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114 JCAHO Manual, supra, n. 16, at 284 (Intent of MS.5 through MS.5.1.2) (emphasis supplied).
stream to District One could be regarded as the “payment” of a cash equivalent. Unlike Hospital Districts One and Two in this Advisory Opinion, physicians cannot sell, grant or transfer in any way their privileges to practice at a particular hospital. Hospital privileges do not exist as an item of discrete value which can be paid or transferred to another. They are not “remuneration.”

A hospital’s credentialing function can be analogized to a state’s regulatory function in issuing licenses and permits for various activities – from practicing medicine to hunting and fishing. The United States Supreme Court has determined that the issuance of a license constitutes the granting of authority as opposed to the transfer of valuable property. In *Cleveland v. United States*, a case which bears some analogies to the present situation, the Supreme Court held that the issuance of a video poker license by the state of Louisiana did not amount to a transfer of property to the applicant. The Court noted that even though Louisiana might derive some financial benefit from the issuance of video poker licenses (through the generation of licensing fees), the primary function in issuing such permits was regulatory: “It rests... upon the State’s sovereign right to exclude applicants deemed unsuitable to run video poker operations. A right to exclude in that governing capacity is not one appropriately labeled “property.””

The Cleveland decision makes an important distinction in the context of defining “property” for purposes of the federal Hobbs Act extortion statute, 18 U.S.C. 1951. Cleveland held that a government license in the hands of the government is not “property.” However, once the license is in the hands of the licensee, it may constitute property, if it is transferable and therefore has a market value. Medical staff privileges are never transferable; they have no market value; accordingly, they are not “property” under the *Cleveland* jurisprudence. Yet if the grant of privileges is not a “payment” within any

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116 Id. at 24
conventional sense of that word and not “property” within the Supreme Court's jurisprudence, in what sense can it be remuneration?

The Hospital’s power (and obligation) to regulate physicians through the credentialing process is a regulatory function, and an unissued grant of medical staff privileges is not “property” or “remuneration” which may be “transferred” by the Hospital to the physician -- or from one physician to another -- within the meaning of the Anti-kickback Act.

3.2.7 Greber and Bay State Ambulance

The two cases most often cited in support of the breadth of the concept of “remuneration” are United States v. Greber,\textsuperscript{117} and United States v. Bay State Ambulance.\textsuperscript{118} However, neither of these case support a departure from the basic principle that remuneration involves payment or transfer of cash or a cash equivalent. In fact, the discussions in Greber and Bay State actually reinforce that view.

*Greber* involved payments made by a laboratory to physicians referring patients for Holter-monitor tests. The defense in Greber was that the payments were not kickbacks but compensation for legitimate “interpretation” services rendered by the referring physicians in consulting and explaining test results to patients. The court concluded otherwise. It found that the “interpretation” fees were not legitimate compensation, but actually payments made (in whole or in part) for the specific purpose of inducing referrals.

The specific issue that the court grappled with was whether the term “remuneration” extends to reach a situation in which *some* legitimate service is performed for the payment rendered. The court concluded that it did. In reaching its result, the court compared the term “remuneration” and the term “kickback,” and concluded that while a “kickback” refers to a payment for which *no* legitimate service is rendered and the only reason for the payment is the inducement of referrals, “remuneration” refers to a situation in which *some*

\textsuperscript{117} United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

\textsuperscript{118} United States v. Bay State Ambulance, 874 F.2d 20 (1st Cir. 1989).
legitimate value is received for the payment rendered but it is still evident that at least “one purpose” of the payment was the inducement of referrals.\footnote{Greber, supra, n. 117, at 71-72. With regard to the definition of “remuneration” the court stated as follows: “The text refers to “any remuneration.” That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended. “Remunerates” is defined as “to pay an equivalent for service.” Webster Third New International Dictionary (1966). By including such items as kickbacks and bribes, the statute expands “remuneration” to cover situations where no service is performed. That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist. . . By adding “remuneration” to the statute in the 1977 amendment, Congress sought to make it clear that even if the transaction was not considered to be a “kickback” for which no service had been rendered, payment nevertheless violated the Act.”}

The court’s discussion makes it clear that what is at issue in either the case of a “kickback” or of “remuneration” is a payment. Extension of that concept to the granting of medical staff privileges is not even remotely suggested or implied by Greber.

In Bay State Ambulance, the issue was also whether payments which were made at least in part as compensation for legitimate services rendered could also constitute illegal “remuneration” under the Anti-kickback Act. That case involved compensation paid by Bay State Ambulance Company to a part-time consultant, John Felci, who was at the same time also an employee of the Quincy City Hospital in charge of the oversight of the hospital’s ambulance contract with Bay State. The evidence showed that Felci had been very instrumental in securing a renewal of Bay State’s ambulance contract at a time when he was also receiving cars and cash payments as Bay State’s consultant. The government alleged that the payments from Bay State to Felci were made at least in part in exchange for Felci’s services in arranging for the ambulance contract, and therefore a violation of the Anti-kickback Act.\footnote{The Anti-kickback Act makes it illegal, \textit{inter alia}, to solicit, receive, offer or pay remuneration in exchange for arranging for or recommending any service for which payment may be made under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(1)(B) and (2)(B) (emphasis supplied). In Bay State, this provision of the statute was held to encompass a series of acts by Felci designed to influence the selection process in Bay State’s favor.}

As in Greber, the issue in Bay State Ambulance was whether payments that were made at least in part as compensation for legitimate consulting
services, could also be “remuneration” prohibited by the Anti-kickback Act. Citing Greber, the First Circuit held that the payments could constitute illegal remuneration if the “primary purpose” of the payments was the illegal inducement of referrals. In this context, the First Circuit noted that “giving a person the opportunity to earn money [i.e., the consulting fees] may well be an inducement to that person to channel potential Medicare payments toward a particular recipient.”\textsuperscript{121} There was no suggestion, however, that “remuneration” could be extended to cover something other than a cash or in-kind payment. Therefore, \textit{Bay State} does not support the notion that the granting of medical staff privileges could constitute “remuneration.”

3.2.8 The Cross-Referral Safe Harbor

The OIG, in adopting the cross-referral safe harbor in 1999, did suggest that under certain circumstances an \textit{agreement to direct referrals} could constitute “remuneration.” This is perhaps the furthest that the OIG has gone from the concept of “remuneration” as a discrete “payoff.” The cross-referral safe harbor specifies the circumstances under which a physician may agree to refer a patient to a second physician on condition that the second physician agrees to refer the same patient back to the original physician. The mutual exchange of the right to a specific referral flow is analogous, in some respects, to the transfer of the exclusive right to the referral flow associated with Hospital District Two in Advisory Opinion No. 99-4, discussed in Section 3.2.1.5, above. The OIG expressed concern that such arrangements could be abusive in certain circumstances, particularly where there is any type of financial payment or fee splitting involved in the referral exchange.\textsuperscript{122}

In order for a cross-referral arrangement to be even a potential violation of the Anti-kickback Act, however, the OIG had to conclude that, under certain circumstances, the directing of a referral from one physician to another could itself constitute “remuneration.” The OIG cited the \textit{Bay State Ambulance}
case as authority for the proposition that “the opportunity to generate a fee may constitute the requisite remuneration under the statute, even if no payment or rebate is paid for a referral.” As noted in the previous section, *Bay State* actually involved direct compensation in the form of consulting fees and in-kind payments to the individual – Felci -- who was in a position to control the referral of Medicare business to Bay State. The “opportunity to generate a fee” noted by the OIG was simply the granting of the consulting contract pursuant to which Bay State paid Felci. In the cross-referral situation, the “opportunity to generate business” would presumably be the referral of a patient whom the receiving physician could bill a third party for. Therefore, the analogy between the *Bay State* situation and a cross-referral arrangement is imperfect, at best.

In any event, the notion of a referral exchange is very distant conceptually from the grant of medical staff privileges. Physicians control Medicare fee-generating business directly. Hospitals merely provide the setting in which Medicare fee-generating services can occur. For a physician to send a Medicare patient to a colleague will result in a direct and certain generation of a Medicare fee – just as Bay State’s granting of a consulting contract to Felci resulted in a direct and certain generation of a consulting fee to Felci. By contrast, for a hospital to grant privileges to a physician merely permits that physician to practice in that setting. Therefore, the “cross-referral” safe harbor does not help illuminate whether the granting of medical staff privileges could constitute “remuneration.”

3.2.9 Practical Considerations

To include a concept such as the granting of medical staff privileges in the definition of “remuneration” would simply be unworkable. Medical staff privileges are universally required for practice in a hospital setting. Every physician who practices at a hospital must have privileges there. And every physician who has privileges at a hospital makes referrals to that hospital within

123 *Bay State Ambulance*, supra, n. 118.
124 64 Fed. Reg. at 63549.
the meaning of the Anti-kickback Act. Consequently, if the granting of privileges is “remuneration,” then every single time a hospital grants privileges to a physician, it is potentially committing a crime. In the absence of a safe harbor explicitly permitting the granting of medical staff privileges and defining the circumstances under which medical staff privileges may be granted, then every Hospital (and every physician) has already potentially committed countless felonies since 1977, when the language of the Anti-kickback Act was expanded to include the term “remuneration.”\textsuperscript{125} That notion is absurd.

The comments of Judge John W. Lundstrum of the District Court of Kansas seem particularly apt here. Judge Lundstrom, in the well-known Anti-kickback Act case of \textit{United States v. Anderson}\textsuperscript{126} arising out of a series of consulting agreements between the Baptist Medical Center and the Blue Valley Medical Group (“BVMG”), dismissed the government’s case against two attorneys who had assisted in the negotiation of the contracts. In entering his order of dismissal, Judge Lundstrom made the following comments regarding the lawyers’ role, which illuminate the broader dilemma that all hospitals face in navigating the treacherous waters created by the Anti-kickback Act:

The problem here is that a very simple concept, “payment for patients is illegal,” became far from simple as Congress, the Executive Branch and the Courts got more deeply involved. “Remuneration to induce” language invites judicial interpretation as to what these words mean – indeed the government in this case adamantly maintains that the words require definition as part of the jury instructions. Judicial catch phrases like “one purpose rule” or “primary purpose rule,” the reversals of the field by the OIG concerning its own interpretation, the checkered history of the \textit{Hanlester} case and the reservation by Congress of a safe harbor provision in the Act (the promulgation of regulations concerning which were delayed for a considerable period of time) all invite lawyers to attempt to devise

\textsuperscript{125} The OIG has stated in its safe harbor commentary that “because the statute is broad, the payment practices described in these safe harbor provisions \textit{would be prohibited by the statute but for their inclusion here.}” 56 Fed. Reg. 35952 at 35958 (emphasis supplied).

legal ways for parties to have a relationship which has as a component hoped-for and anticipated referrals . . .  

The alleged kickbacks at issue in the Anderson case involved the actual exchange of money, not the granting of medical staff privileges. If “remuneration” now includes medical staff privileges, then hospitals will be obliged to seek legal counsel on every credentialing decision, and the problems articulated so well by Judge Lundstrom will become magnified exponentially.

The Anti-kickback Act has already caused considerable confusion for the healthcare industry, spawning six statutory exceptions, six fraud alerts, seventeen safe harbors and nearly ninety Advisory Opinions directed towards defining acceptable and unacceptable payment practices. If the OIG now embarks on a mission of creating safe harbors to define acceptable and unacceptable privileging practices the entire industry will grind to a halt. The process of analyzing every credentialing decision for possible fraud and abuse implications would create an administrative and regulatory nightmare.

“Remuneration” means payment of cash or a cash equivalent. This concept simply cannot be extended to encompass the process of granting medical staff privileges.

3.3. The “Knowing and Willful” Requirement

The other limiting factor on the breadth of the Anti-kickback Act is the requirement that the payment in exchange for referrals have been “knowing and willful.” The courts have disagreed on the degree of scienter required for a violation of the Anti-kickback Act. In Hanlester v. Shalala,128 the Ninth Circuit held that the “knowing and willful” language required the government to prove

127 Id, Trial Transcript, page 7342-45. This passage is quoted in the District Court’s opinion in United States v. Anderson, 85 F. Supp. 2d 1047, 1064-65 (D. Kan. 1999), aff’d sub nom United States v. LaHue, 170 F.3d 1026 (10th Cir. 1999). See, Mustokoff and Nagele, supra, n. 52 at 17.

that the defendant acted with “specific intent to disobey the law.” Other Circuits have adopted a less stringent standard. For instance, in United States v. Davis, the Fifth Circuit upheld a jury instruction that defined “willfully” as acting “with the specific intent to do something that the law forbids; that is to say, with a bad purpose to disobey or disregard the law.” The Eleventh Circuit, in United States v. Starks, held that “willfully” means that the defendants “knew that they were acting unlawfully.” In United States v. LaHue, the Tenth Circuit upheld a jury instruction that stated that the government must prove that the defendant acted with “specific criminal intent “to induce” referrals.”

While each of these cases applied a slightly different legal standard, they consistently recognize that in order to be held criminally accountable for violations of the Anti-kickback Act, a defendant must be shown to have specific knowledge that he was acting wrongfully or violating the law. In order for that to occur, there must have been some clear notice to the defendant that the conduct engaged in was a violation of the law. At a minimum, the “rule of lenity” requires that any ambiguities in a criminal statute are to be resolved in the defendant’s favor. The “rule of lenity” is premised on the concept that “fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed.”

In the case of medical staff credentialing, there is no reason why a hospital should have any reason to believe that any form of credentialing activity could give rise to a potential violation of the Anti-kickback Act. As discussed above, the statute, the regulatory guidance and judicial interpretation have consistently defined “remuneration” as some form of cash or cash equivalent—which the granting of medical staff privileges clearly is not. The Request for

129 Id. at 1390.
130 United States v. Davis, 132 F.3d 1092, 1994 (5th Cir. 1998)
132 United States v. LaHue, 261 F.3d 993, 1003 (10th Cir. 2001).
Comment published by the OIG on December 9, 2002 is the first time that the OIG has even remotely suggested that it would consider the possibility that certain forms of credentialing could constitute “remuneration.” Furthermore, the fact that the OIG has, at the urging of the AMA, requested comments on this topic, should not create any presumption that it will ultimately agree with the AMA’s position on this issue.

No statute, regulation, judicial opinion, OIG fraud alert, OIG comment or OIG advisory opinion has ever intimated that a hospital's grant of privileges constitutes remuneration. An attempt to force such a reading of the criminal Anti-kickback statute would likely be held Constitutionally deficient as too vague to have supplied fair notice to putative defendants that a crime of this sort even existed. Under the Due Process Clause of the Fifth Amendment, the void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited and in a manner that does not encourage arbitrary and discriminatory enforcement. *Posters 'N' Things v. United States*, 511 U.S. 513 (1994). On the legislative and judicial history of Anti-kickback Act "remuneration," that Constitutional standard simply cannot be met.

In the absence of any suggestion in the statute, judicial interpretation or regulatory guidance that medical staff privileges could constitute “remuneration” for purposes of the Anti-kickback Act, it would be irrational to determine that a hospital had violated the Act based upon its credentialing activities. Furthermore, even if the OIG were now to move forward with the development of a safe harbor for credentialing, given the legislative history, a reasonable question can be raised as to whether it would be within the OIG’s statutory authority to determine that the grant of medical staff privileges can constitute “remuneration” within the meaning of the Anti-kickback Act.

### 3.4 The OIG’s Call for Comments on Economic Credentialing

The OIG’s recent Solicitation of Public Comments on Certain Credentialing Practices indicates that, notwithstanding the fact that it represents
a major departure, the OIG is now willing to at least consider the possibility that the granting of (or, more precisely, the refusal to grant) medical staff privileges could constitute “remuneration” under certain circumstances.\(^\text{134}\) The OIG recites that there are three specific areas in which issues could be raised under the Anti-kickback Act as a consequence of a hospital’s refusal to grant medical staff privileges. The OIG is interested in refusals to grant privileges to physicians who (1) own or have other financial interests in, or leadership positions with, competing healthcare entities (i.e., conflict of interest Policies), (2) refer to competing health care entities or (3) fail to admit some specified percentage of their patients to the hospital.\(^\text{135}\) In order to help it assess these issues, the OIG has asked for comments in five specific areas:

(A) Are hospital staff privileges “remuneration?” Are there circumstances under which they could be seen as having demonstrable monetary value?
(B) What are the implications of a hospital’s denial of privileges to a physician who competes with the hospital?
(C) Should the exercise of discretion by the privilege-granting hospital affect the analysis under the Anti-kickback statute?
(D) Can privileges ever be conditioned on referrals, other than minimums necessary for clinical proficiency?
(E) What is the effect of credentialing restrictions that apply only to members of a group practice?\(^\text{136}\)

The questions raised are good ones, and begin to illuminate some of the complexities which would arise if the OIG were to attempt to regulate economic credentialing practices through its interpretive authority under the Anti-kickback Act. Without intending to be exhaustive, we will therefore offer our perspective on the issues that have been raised.

(A) Are hospital staff privileges “remuneration?” Are there circumstances under which they could be seen as having demonstrable monetary value?

\(^{134}\) 67 Fed. Reg. at 72895.
\(^{135}\) Id.
\(^{136}\) Id.
We have already set forth at length the reasons why hospital staff privileges are not “remuneration” under the Anti-kickback Act, and that to attempt to include them in the definition of “remuneration” would be an unwarranted extension of the language and intent of the Act itself. However, the OIG has raised some interesting questions as to whether medical staff privileges can be seen to have “demonstrable” economic value, which warrant a serious response.

The OIG’s first question is whether hospital privileges have taken on a greater economic significance in some areas due to the combined growth of managed care networks and dominant health systems that limit access to hospital privileges and to patients. The OIG also asks whether, assuming that is true, whether those facts provide a basis for concluding that medical staff privileges are “remuneration.” We acknowledge that the combined effect of managed care networking and dominant health systems can have the effect of limiting physicians’ access to both hospitals and patients, and can also thereby increase the economic importance to individual practitioners of having medical staff privileges. However, we do not believe that the economic value of such privileges can be quantified in a specific or meaningful way.

We have already pointed out that medical staff privileges are a grant of authority, and cannot be bought, sold or transferred. Whatever economic value privileges have is not based on any intrinsic quality, but is the result of whatever the individual physician chooses to make of them. Physicians practicing identical specialties in the same hospital could have vastly different incomes based on areas of subspecialty, payer and patient mix, hours worked, how much time they spend marketing, what other professional or personal obligations they may have, and so on. The “value” of medical staff privileges – even within the same hospital -- will vary vastly based on all of these factors. When one starts to compare different hospitals, different geographic areas, different specialties, and so forth the potential for variation grows exponentially. The existence of managed care networks and dominant health systems are just two of the many
factors affecting the value of a set of privileges at a particular hospital to a particular physician. It would be difficult, if not impossible, for the OIG to attempt to define the “economic value” of medical staff privileges based upon any of these factors – or to create a special category of medical staff privileges that qualify as “remuneration” based upon some determination of their economic value. There are just too many variables involved to draw any meaningful distinctions.

Moreover, it would be irrelevant for the OIG to attach a value to the medical staff privileges of a physician who has been excluded from medical staff privileges, because exclusion is not a violation of the Anti-kickback Act. The Act prohibits the “solicitation, receipt, offer or payment” of remuneration – not the denial of remuneration. Therefore, to make out a case under the Anti-kickback Act, the OIG would need to focus not on the physicians who have been denied privileges, but the physicians who have been granted privileges. This would, presumably, require an evaluation and determination as to whether the privileges granted to each of the included physicians had sufficient economic value to those physicians to constitute remuneration. Again, each one of those valuations would be subject to a whole host of individualized factors, and would even be subject to fluctuations over time.

Staff privileges are not “cash equivalents,” they are licenses. A physician can maintain privileges at a hospital for a period of time, and never step foot in the hospital. Another physician can maintain privileges at the same hospital, and generate income exceeding a million dollars a year. There is no rational or logical basis on which the government could attempt to define the “economic value” of credentials for any particular physician, any specialty, any practice setting, any geographic reason, or on any other basis.

(B) **What are the implications of a hospital’s denial of privileges to a physician who competes with the hospital?**

This question raises directly the issue of whether Conflict of Interest policies violate the Anti-kickback Act. Conflict of Interest policies can
disqualify physicians for medical staff membership base on ownership/investment interests, compensation relationships or leadership positions in competing facilities such as Ambulatory Surgery Centers. In our view, such policies do not implicate the Anti-kickback Act.

Initially, we note that the OIG already agrees that “a credentialing policy that categorically refuses privileges to physicians with significant conflicts of interest would not appear to implicate that [sic] anti-kickback act in most situations.”137 Since the categorical exclusion is, in our experience, the predominant format for Conflict of Interest policies, the OIG’s comment suggests that the vast majority of such policies would not even be questioned by the OIG.

Moreover, it should be noted that Conflict of Interest policies impact on different categories of physician in different ways. As to those physicians who are denied or disqualified from medical staff membership/privileges, there is no Anti-kickback violation, because, as noted above, denials of “remuneration” do not give rise to Anti-kickback Act violations. As to those physicians who remain qualified for medical staff membership/privileges, they remain qualified regardless of the volume or value of any referrals to the Hospital. If they make no referrals at all, they are equally qualified under the Policy as if they made 100 referrals per month. The agreement not to maintain an ownership/investment or compensation relationship is not the equivalent of an agreement not to refer elsewhere: physicians remain free to exercise their medical judgment and refer patients to whatever facility they believe is medically appropriate. Thus, even if the OIG were to conclude that medical staff privileges are remuneration, it would not be self-evident that the non-conflicted physicians were allowed to remain on staff in exchange for referrals since those physicians would be under no obligation to refer any patients to the hospital in any event. An even-handed Conflict of Interest Policy applied in a

uniform manner to all practitioners and not requiring any doctor to actually refer any patients to the hospital could hardly be construed as the granting of privileges in exchange for referrals.

(C) Should the exercise of discretion by the privilege-granting hospital affect the analysis under the Anti-kickback statute?

The OIG raises an interesting issue when it questions whether a conflict of interest policy which does not categorically exclude any physician from the medical staff based on a competing interest, but rather, gives the Hospital the discretion to grant or deny privileges would raise any greater concern under the Anti-kickback Act. Of course, in our view, the element of discretion would be irrelevant since the granting of privileges is not “remuneration” in any case.

However, assuming that the OIG were to conclude that, under some circumstances, the granting of privileges can constitute remuneration, then certainly the element of discretion would be relevant because it would open the door to a consideration by the hospital as to the likelihood that the physician would “refer” patients – i.e., admit and treat them at the hospital -- if the privileges were granted. In point of fact, however, it is unrealistic to think that any credentialing review under any circumstances is completely devoid of consideration as to whether the physician is likely to admit and treat patients. In fact, hospitals are required to give consideration to such issues. For instance, the JCAHO standards specify that the decision to grant privileges is based not only on the applicant’s training and qualifications, but also based on “the procedures and types of care or services that can be performed or provided in the hospital.” The standards provide further that “if an applicant’s training or experience is in a specific area(s), corresponding privileges can be granted only if the hospital has adequate facilities, equipment, number and types of qualified support personnel, and necessary support services.”138

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138 JCAHO Manual, supra, n. 16, at 284 (“Intent of MS.5 through MS.5.1.2”)
necessarily take into account the physician’s projected usage – i.e., the volume of patients expected to be admitted to and treated at the Hospital. Likewise, a hospital’s ability to perform adequate quality assurance and risk management is a function, at least in part, of the physician’s volume of activity at the hospital. If hospitals had to be concerned about taking these factors into account in credentialing decisions, this would seriously impair their ability to do the job effectively.

The element of discretion certainly opens the door to a consideration of the physician’s potential to generate referrals (also known as patient volume) for the hospital. However, these considerations are essential considerations for hospital management and planning. To introduce the possibility that a hospital’s consideration of those factors in credentialing decisions would potentially subject it to criminal prosecution under the fraud and abuse law would be devastating to the hospital industry.

(D) Can privileges ever be conditioned on referrals, other than minimums necessary for clinical proficiency?

In our view, since the granting of privileges is not remuneration, there is no Anti-kickback impediment at all to a hospital’s conditioning privileges on a physician’s commitment to performing a certain percentage of his practice at the Hospital. Moreover, even assuming that privileges were found to be “remuneration,” in our view, as a policy matter, hospitals should be able to take the full range of economic factors into account in making credentialing decisions, without fear of criminal sanctions.

As discussed in the first section of this article, hospitals are under extreme pressure from both market and regulatory forces to streamline their operations, making them efficient and cost-effective. In many cases, hospitals are operating on very thin margins, or in a deficit situation. Of necessity, hospitals must consider economic factors in every aspect of their operations – including the activities of their medical staffs. In some cases, this may include setting minimum volume requirements as a condition of granting privileges.
Hospitals must be able to predict with accuracy their patient volumes in each area of specialty, so that their use of space, equipment and personnel is efficient, and so that they can plan effectively for their future needs. In some cases hospitals may need to guarantee certain minimum usages in order to justify maintaining existing equipment and personnel or making the capital investment required for new programs. The fear of criminal prosecution would completely chill hospitals’ efforts in this regard, and subvert the drive towards economic efficiency.

The OIG appears to acknowledge that some volume requirements may be acceptable – such as (1) the minimum number required to ensure adequate data for quality assurance purposes, or (2) in a case of a hospital with failing financial health, or (3) where a certain volume is required to support a critical service that would otherwise not be available to the community. It also suggests that certain other volume requirements would be suspect – such as a requirement that 75% of a physician’s patients be admitted to the hospital. The problem is that it would be extremely difficult for the OIG to develop a set of “bright-line” standards in this complex area that would be sufficiently clear that they could be followed by hospitals without fear of risking criminal sanctions. Ironically, the creation of such standards would likely lead to a much more cumbersome and inefficient credentialing process, with layers of administrative and legal review, which would increase the hospitals’ cost and burden at a time when they are under enormous pressure to become more efficient in every aspect of their operations.\textsuperscript{139}

Declaring medical staff privileges to be “remuneration” under any circumstances would open a pandora’s box and create an enormous new regulatory burden on hospitals. It would not be possible to declare some types

\textsuperscript{139} The last question asked by the OIG inquired as to the impact of credentialing restrictions on one or more members of a group practice. This is a fairly discrete issue as to which we do not offer any specific views, other than to reiterate that there no legal impediment to any type of credentialing restriction because privileges are not “remuneration” and credentialing is not an area of concern under the Anti-kickback Act.
of credentialing unlawful without creating an entirely new framework for analysis requiring every medical staff decision to be evaluated for potential fraud and abuse exposure.

4. The New Threat: A False Claims Act Challenge to Economic Credentialing

One of the recent legal developments which has engendered renewed interest in the question of whether the Anti-kickback Act provides a basis for challenging hospital’s economic credentialing initiatives is the increased use by private litigants of the *qui tam* provisions of the False Claims Act in challenging hospital behavior under the Anti-kickback laws. In fact, this avenue has been specifically suggested as means by which physicians could challenge hospitals’ economic credentialing policies.\(^\text{140}\) However, for a number of reasons, False Claims Act litigation does not present the right battleground for resolving the economic credentialing debate.

4.1 The False Claims Act

The False Claims Act ("FCA")\(^\text{141}\) is a powerful federal statute that creates liability for the submission of false claims to the federal government.\(^\text{142}\) It was enacted originally in the Civil War era as a means of remedying fraudulent conduct by government contractors who were billing the government for work that was never performed or products that were not delivered.\(^\text{143}\) However, in the past decade, it has been used aggressively by the government as

\(^{140}\) Raspanti and Laigaic, supra, n. 5, at 328.
\(^{141}\) 31 U.S.C. § 3729 *et seq.*
\(^{142}\) Lisa Michelle Phelps, “Calling off the Bounty Hunters: Discrediting the Use of Alleged Anti-kickback Violations to Support Civil False Claims Actions,” 51 Vand. L. Rev. 1003 (1998).
a vehicle for combating Medicare fraud, resulting in billions of dollars of recovery through settlements and verdicts.\textsuperscript{144}

The False Claims Act has both criminal and civil provisions.\textsuperscript{145} The civil False Claims Act, 31 U.S.C. § 3729 creates liability for seven specific types of fraudulent conduct. The three most cited provisions in health care fraud cases are sections (1), (2) and (7), which impose liability on a person who:

1. knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]

7. knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.\textsuperscript{146}

The penalties for violation of this provision are $11,000 per claim plus treble damages for the amount of the loss sustained by the government as a result of the fraudulent conduct.\textsuperscript{147} Since the government takes the position that each and every claim for reimbursement under a Federal program is a separate “claim” for purposes of the penalty provision, the potential liability under the FCA can quickly become astronomical.\textsuperscript{148}

The civil False Claims Act also has a \textit{qui tam} whistleblower provision, which is one of the major factors in its emergence over the last decade as such a

\textsuperscript{144} See, Department of Justice, \textit{Justice Department Recovers Over $1 Billion in FY 2002}, at www.usdoj.gov. (Dec. 16, 2002) (For the fiscal year ending September 30, 2002, recoveries in civil fraud claims reached nearly $1.2 billion. Suits involving health care fraud accounted for more than $980 million of the total.).

\textsuperscript{145} The criminal provisions are codified at 18 U.S.C. § 287. The civil provisions are codified at 31 U.S.C. § 3729 \textit{et seq.}

\textsuperscript{146} 31 U.S.C. § 3729(a)(1), (2) and (7).

\textsuperscript{147} 31 U.S.C. § 3729(a); see also, 64 Fed. Reg. 47099, 47104 (updating penalty provision to $11,000 per claim).

\textsuperscript{148} See, Boese and McClain, supra, n. 143, at 18-19.
prominent litigation tool. The *qui tam* provisions authorize private citizens to bring FCA actions in the name of the government. Any potential *qui tam* plaintiff may file a suit alleging FCA violations and claiming the fines and penalties provided under the statute in the name of the government. When such cases are filed, the private “relator” is required to share the factual information that he or she has with the Department of Justice, which may then elect to intervene in the suit and pursue it in its own name. However, even if the government decides that the case is not meritorious enough to intervene, the private relator may still pursue the case, unless both the Attorney General and the court authorize a dismissal of the action.

There are very powerful financial incentives for private litigants to pursue such cases. A prevailing private relator, in a case in which the government has opted not to intervene, can obtain up to thirty percent of any financial recovery (by way of settlement or verdict) which, as noted earlier, can be astronomic in these types of cases. In addition, there is a separate attorney fee provision pursuant to which the relator’s attorneys may recover their fees directly from the defendant in any case which produces a financial recovery for the government. Because of these powerful financial incentives, for the fiscal year ending September 2002, a total of more than 300 *qui tam* cases have been filed.

### 4.2 The Controversial Use of the Anti-kickback Act as a Predicate to a False Claims Act Cause of Action.

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151 31 U.S.C. § 3730(a). As a practical matter, such dismissals are extremely rare. In our experience, even if a government prosecutor has determined that a case is not meritorious, he or she will rarely take affirmative action to dismiss it. More likely, the prosecutor will simply stand by and wait to see whether the private “relator” succeeds in his or her theory.
153 Id.
The use of the FCA as a means of obtaining civil recoveries for alleged violations of the Anti-kickback Act, was spawned by two cases decided in the mid-1990s, i.e., the 1996 Tennessee district court decision in *U.S. ex rel. Pogue v. American Healthcorp. Inc.*\(^{155}\) and the 1998 Fifth Circuit decision in *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*\(^{156}\) These two cases applied, for the first time, the “false certification” doctrine which had developed through judicial interpretation of the FCA.

Under the “false certification” doctrine, liability is predicated not on the submission of a “false claim” *per se*, but on the submission of a “false certification” that claims which have been submitted for reimbursement by the federal government have been submitted in compliance with all applicable laws and regulations.\(^{157}\) The most common application of the “false certification” doctrine to hospitals is through the annual cost report which hospitals are required to submit annually to the federal government as a condition of participating in and receiving reimbursement through the Medicare Program. The annual cost report provides detailed data to the government regarding the cost of services provided by the participating provider during the course of the prior year, and is used for purposes of calculating and adjusting the amounts owed to hospitals under the Medicare program.

In this annual cost report, hospitals are required to submit an annual certification that the services they have provided through the Medicare program were done so in accordance with all applicable laws and regulations. The certification does not specifically reference the Anti-kickback Act, but an accompanying statement acknowledges that the officer or administrator signing the cost report is aware of the fines and penalties associated with the payment of

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\(^{157}\) Id.
The “false certification” theory posits that, if a hospital submits a cost report certification despite having violated the Anti-kickback Act during the course of the previous year, then a fortiori, it has violated the False Claims Act.\(^\text{159}\) In fact, it has been argued that under this theory, an Anti-kickback violation could become an \textit{per se} or \textit{ipso facto} violation of the False Claims Act because “any claims ‘tainted’ by the kickbacks were ineligible for payment by the government.”\(^\text{160}\)

The Anti-kickback application of the “false certification” theory has withstood Motions to Dismiss in a number of different jurisdictions since the mid-1990s, but it has come under substantial criticism as well. The principle concern is that this theory turns the FCA into a vehicle for permitting private civil litigants to take over the government’s job of enforcing this criminal statute.\(^\text{161}\) There are three important reasons why this is inappropriate: first, the Anti-kickback Act nowhere authorizes a private right of action;\(^\text{162}\) second, permitting private enforcement of the Anti-kickback Act under the FCA has the potential for altering the standards of proof and intent in Anti-kickback Act cases; third, the remedial schemes for the two statutes are inconsistent and potentially conflicting.

The most significant criticism of using the FCA for Anti-kickback enforcement is that the Anti-kickback Act simply does not create a private right

\(^{158}\) The text of the required cost report certification may vary slightly from year to year, but has two relevant provisions. The first is an affirmation by the signing officer or administrator that he has read the following statement: “... FURTHERMORE, IF SERVICES IDENTIFIED BY THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.” The second is a certification by the signing officer or administrator that: “... I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.”

\(^{159}\) Phelps, supra, n. 142, at 1016.


\(^{161}\) Boese and McClain, supra, n. 143, at 49-50; Phelps, supra, n. 142, at 1027-28.

\(^{162}\) Phelps, supra, n. 142, at 1029-30.
of action or contemplate enforcement through private litigants. Neither the Act itself nor its legislative history suggests that Congress intended to provide qui tam plaintiffs with a right of action. 163 Multiple courts that have reviewed this issue have determined that there is no private right of action under the Anti-kickback Act. 164 Private litigants do not possess independent standing to enforce the Act, because it is a criminal statute and its enforcement lies squarely in the hands of the federal government. 165 One of the specific concerns with putting the decision as to whether to file suit in the hands of private civil litigants is that it obviates the exercise of prosecutorial discretion, under which the government has the obligation to make a reasoned decision as to whether the defendant’s conduct in any particular case warrants prosecution. In the words of one commentator: “[H]ealth care providers today are expected to operate in an almost Kafkaesque environment, where conventional conduct is made illegal and where the government is permitted broad prosecutorial discretion, the exercise of which is unpredictable and subject to being overruled by both private citizens and other branches of government.” 166 Placing the decision on this issue into the hands of private qui tam relators appears to be at direct odds with the government’s expressed policy of promoting a more deliberative process in its exercise of prosecutorial discretion in health care fraud litigation. 167

A related significant concern with allowing FCA cases to be brought as vehicles for Anti-kickback Act enforcement is that to do so fundamentally alters both the elements of proof and the Act’s remedial scheme. The Anti-kickback Act is a criminal statute which requires proof of criminal intent: in order to have committed the crime, the defendant must have acted “knowingly and willfully.” (emphasis supplied). The FCA is a civil statute that requires only that the

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163 Id.
165 Id.
166 Boese and McClain, supra, n. 143, at 49-50.
defendant act “knowingly.” There is a significant difference between the degree of *scienter* required for violations of these two acts. Consequently, at the very least, there is a significant potential for jury confusion as it struggles to apply two different standards to two different aspects of the same case. At worst, the risk exists that for any case going forward as an Anti-kickback based FCA case, that the higher criminal intent standard required for the Anti-kickback element of the offense will be overlooked or eliminated.

A similar potential for confusion exists by virtue of the different standards of proof applicable for criminal and civil actions. Under the Anti-kickback Act, a defendant is entitled to a presumption of innocence unless guilt is proven beyond a reasonable doubt. Under the FCA, the standard of proof is preponderance of the evidence. Linking the two, therefore, creates at least the potential that a defendant in an Anti-kickback based FCA case will lose the benefit of the presumption and higher standard of proof.\(^{168}\)

Finally, the two statutes have different remedial schemes, and allowing Anti-kickback claims to be prosecuted as FCA violations would permit courts to award potentially huge monetary sanctions for Anti-kickback Act violations never contemplated in the Act itself. The Act is a criminal statute which provides for fines of up to $25,000 and imprisonment of up to 5 years. The FCA provides for penalties of up to $11,000 per claim and treble damages.\(^{169}\) There is no reason for making the FCA statutory remedies available for kickback violations.

Notwithstanding these serious concerns with pairing the Anti-kickback Act and the FCA, the Anti-kickback Act-based FCA cause of action is being advocated as a means for private parties to challenge hospitals’ economic credentialing practices.

\(^{168}\) Phelps, supra, n. 142, at 1026-27.

\(^{169}\) In addition, for Anti-kickback or FCA violations, the OIG has been given the authority to develop its own civil remedies. Those include: penalties of $50,000 per claim, treble damages, and exclusion from participation in the Medicare program for some period of time, or permanently.
4.3 Critique of the Use of the Anti-kickback Act-based FCA Claim as a Vehicle for Challenging Economic Credentialing Practices.

When one considers together (1) the tenuousness of the concept that the granting of hospital privileges could constitute a kickback violation and (2) the strong policy reasons for not allowing the FCA to become a private Anti-kickback Act enforcement vehicle, it becomes readily apparent that the legal theory supporting the use of the FCA as a means of challenging economic credentialing is built on straws. The adoption of such an approach to regulating economic credentialing would stretch both the Anti-kickback Act and the FCA beyond all recognition.

Stripped to its core, the legal theory supporting this cause of action would have to be as follows: (1) Hospital A granted privileges to Drs. X, Y and Z, at least in part (i.e., the “one purpose rule”) because it wanted the financially attractive referral streams that it anticipated its hospital would receive by virtue of having those physicians practicing at its hospital; (2) the privileges at Hospital A were economically valuable to Drs. X, Y and Z, and therefore constituted “remuneration” to those physicians; (3) Hospital A “knowingly and willfully” “paid” (i.e., granted) such “remuneration” (i.e., the medical staff privileges) to Drs. X, Y and Z with criminal intent to induce the referral streams that those physicians could generate; (4) Hospital A knew that its conduct in granting hospital privileges to Drs. X, Y and Z with the hope of generating valuable referral streams from those physicians was unlawful and in violation of the Anti-kickback Act; (5) When it submitted its cost report for the Medicare program at the end of that year, Hospital A certified its knowledge of the fines and penalties associated with the Anti-kickback Act and that it was in compliance with all applicable laws and regulations; (6) This certification was “false” because of the kickback violations associated with the granting of privileges to Drs. X, Y and Z, and Hospital A knew it was “false;” (7) therefore, every claim submitted in connection with services rendered or ordered by Drs.
X, Y and Z has been “tainted,” subjecting Hospital A to treble damages and fines under the FCA as to each and every one of the claims.

The amorphous quality of such a theory is manifest. The kickback component of the theory has moved from the notion of “payment in exchange for referrals” to a “grant of authority in exchange for an anticipated referral stream.” The FCA component has moved from the notion of “false claims” to “false certification of compliance with applicable laws and regulations.” The combined effect is that instead of having a criminal prosecution for illegal “payment in exchange for referrals” a hospital could be subjected to a civil FCA action simply for including an economic analysis in the process of granting or denying medical staff privileges.

The fact is that hospitals always credential physicians, at least in part, because they expect and desire the referral streams those physicians will generate. Without those referral streams, the Hospitals would cease to operate. Hospitals are mandated by law and under enormous pressure from both governmental and private payers to be efficient and “bottom-line” oriented in their management of their operations – including in the oversight of their medical staff. The proposition that hospitals who successfully implement that level of scrutiny are, by doing so, actually engaging in the granting of “kickbacks” and the submission of “false claims” does not take into account the realities of the health care industry. Hospitals are already whipsawed by all of the competing mandates under which they operate, and faced with devastating consequences for choosing the wrong path. If hospitals come to believe that a mis-step in their approach to the credentialing process could result in millions of dollars of fines and penalties for FCA violations, this alone will have a seriously chilling effect on their ability to effectively carry out this core function.
5. Conclusion

Economic credentialing is an essential means by which hospital governing bodies fulfill their oversight responsibilities and ensure that the health care institutions under their governance continue to remain financially viable and capable of providing quality service to the communities they serve. However, economic credentialing is unpopular with physicians because it is perceived as impacting negatively on the autonomy of individual providers and the quality review function carried out by a hospital’s organized medical staff. Although the process of economic credentialing has consistently withstood legal challenge over the last two decades, a serious challenge is now being advocated, under the Anti-kickback Act and the FCA.

The central issue raised by the application of the Anti-kickback Act to economic credentialing is the question of whether the granting of medical staff privileges could under any circumstances constitute a form of “remuneration” as
contemplated by the Anti-kickback Act. A review of all of the prior interpretations of the Anti-kickback Act through legislative history, regulatory commentary and judicial interpretation, has failed to unearth any suggestion that the granting of hospital privileges was ever intended to fall within the scope of the Act. There is a fundamental difference between a hospital’s grant of authority to a physician to practice within its walls, and the making of a financial payoff. Moreover, if hospital privileges are “remuneration” then all hospitals are potentially engaging in criminal activity each time those privileges are granted. If the OIG were to adopt this stance, it would be obliged to comprehensively revise and expand its “safe harbor” regulations to enable hospitals to continue to carry on this central and critical hospital function.

The legal theory under the FCA is even more attenuated. The FCA exists to combat government fraud. To suggest that the government should regulate economic credentialing based upon the notion that the submission of claims for services to the government that have been “tainted” by a hospital credentialing decision that took economic factors into account strains beyond all recognition the core concepts of both the Anti-kickback Act and the FCA. From both a legal and a practical perspective, the adoption of a False Claims analysis of credentialing decisions would create, for hospitals, potentially limitless exposure based on vague and ill-defined concepts of improper conduct.
About the Author

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