The Doctor's Chart

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MISTAKEN PRIORITIES OF PREEMPTIVE COMPLIANCE: FEDERAL REGULATORS ENHANCE FOCUS ON RURAL PROVIDERS

Perhaps the big health systems make far too easy targets for the palates of the OIG. Or, perhaps their activities have finally, as a result of the billions of greatly needed dollars now pouring into federal coffers, those infamous offenders have finally decided to straighten out and fly right. In any event, for whatever reason, it would seem that federal regulators have trained their sights on what most people would agree are less obvious targets: rural health care providers.

It is of course not as if rural providers have to date enjoyed some sort of exception from federal health care laws. Indeed, with a few exceptions, rural hospitals and physicians are subject to the same catalog of laws and standards with which larger, more urban facilities, must contend. Nor has a new law, enhancing focus on rural providers, recently gone into effect. Still, as a law firm that has a number of medical provider clients located in Wisconsin's many Medically Underserved Areas ("MUAs"), the attorneys of this law firm cannot help but notice an enhanced level of scrutiny with which our clients, as well as a significant number of rural groups/facilities we do not represent, must face. Unfortunately, moreover, despite the fact that there have not been any new laws focusing on ensuring rural compliance that have recently gone into effect, however, with the federal Medicare Prescription-Drug Benefit Bill, Congress stands to turn the heat up even further on rural providers.

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The year 2003 started off poorly for rural providers. In a sign of things to come, a small Michigan hospital on January 8, 2003, pleaded guilty to felony fraud charges and agreed to pay a $1 Million fine, as well as $75,000.00 in restitution. The federal lawsuit stemmed out of an earlier conviction of Jeffery Askanazi, M.D., who was convicted of mail fraud for sending bills to Medicare, Medicaid and private insurance plans for medically-unnecessary services. After convicting Dr. Askanazi, the feds used his record to tie in the hospital also, charging it with 18 counts of mail fraud and 12 counts of wire fraud for accepting payment via mail and wire transfer of fees from Dr. Askanazi's procedures. As part of settlement,

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hospital agreed to a compliance plan and to annual audits of its coding and billing performance.

Many of you reading this might react to the case of the Michigan hospital with a dismissive shrug. After all, it is easy to ascribe the disciplinary action to the blatant nature of the hospital's actions. Unfortunately, however, more innocent actions have also garnered the attention of federal regulators.

When physicians and other healthcare providers think about fraud and abuse, the analysis typically starts and ends with the federal Stark and Anti-Kickback laws. Similar in intent, yet different in application, the Stark and Anti-Kickback laws, broadly defined, are designed to prevent physicians and certain other healthcare providers from making money through the referral of patients for Medicare-reimbursable services. Specifically, the Anti-Kickback Statute establishes criminal penalties with respect to any person who knowingly and willfully offers, pays, solicits, or receives any "remuneration" to induce or in return for: (1) referring an individual to a person or arranging for the furnishing of any item or service payable in full or in part under a federal healthcare program; or (2) purchasing, leasing, ordering, or arranging for any good, facility, service or item payable under a federal healthcare program. "Remuneration" is defined to include the transfer of anything of value, in cash or in kind, directly or indirectly, overtly or covertly.

THE EMERGENCY MEDICAL TREATMENT AND LABOR ACT

Although many of you reading this article who work in private practice probably do not care very much about the Emergency Medical Treatment and Labor Act ("EMTALA"), however, anyone who is responsible for call coverage at any hospital should continue reading. The EMTALA was passed into law by Congress in 1986 as a means of stopping a perceived problem of "patient dumping," it was designed to ensure that hospitals cannot by law turn away patients in poor medical conditions who unexpectedly arrive at the emergency department. The goal is that federally-funded hospitals (<u>every</u> hospital as a result of participation in Medicare) should provide, at the very least, the amount of medical care necessary to assist a patient in need. Specifically, EMTALA requires that any individual who comes to a hospital requesting an examination or treatment for a medical condition must receive an appropriate medical screening examination within the hospital's capability.

While EMTALA became a law close to twenty years ago, as is often the case with federal healthcare laws, changes have been made to the original law several times since it was enacted into law. The most recent changes, which became effective on November 10, 2003, are the subject of this article, along with several salient points which all physicians should understand with regard to EMTALA.

First, EMTALA applies to <u>all</u> hospitals that participate in Medicare and <u>all</u> patients who arrive at such hospitals, regardless of whether or not the individual is a recipient of, or even eligible for, Medicare benefits under the federal program. There are <u>no</u> carve-outs for rural hospitals, patients who lack health insurance, citizenship or those who lack anything else.

Second, there are several standards that apply to the hospital depending on precisely "where" on the campus the patient in question comes to the hospital. The easiest way to understand these standards is to compare them with the three intra-hospital locations referenced in the law.

A. **Dedicated Emergency Department ("DED").** One of the more important changes made by the November 10 final rule, the term "Dedicated Emergency Department" was refined and clarified under the EMTALA proposed rule. A DED was originally defined as an entity that serves as an emergency department ("ED") "a significant portion of the time." Now, federal regulators have streamlined this definition to now hold a DED as an entity that (1) is licensed by the State as an ED; (2) holds itself out to the public as an ED; or (3) during the preceding calendar year, provided at least 1/3 of its outpatient visits for the examination or treatment of

emergency medical conditions ("EMCs"). Under the new rule, the full panoply of protections offered by the EMTALA applies to patients who arrive at the DED.

B. **Hospital Arrivals Outside of DED.** As for patients who arrive at the hospital, but who do not show up at the DED, EMTALA only applies to those patients who show up and in fact experience an EMC. The question of whether the patient in question is actually experiencing an EMC, is not to be resolved through the use of a "product layperson standard." In other words, EMTALA's protections apply to non-DED arriving patients who only to the extent a prudent layperson would conclude that the person has an EMC. The final rule, furthermore, clarified that EMTALA would not apply to patients who begin to receive scheduled or unscheduled outpatient services (although those patients would be protected under Medicare's conditions of participation or state malpractice laws).

C. **Provider-Based Entities.** Significantly, EMTALA obligations have been clarified to read that they will not be applicable with regard to patients who show up at a provider-based entity (i.e., not a hospital), unless the entity meets the definition of a DED under one of the three tests described above. For obvious reasons, this change was the most widely-praised regulatory adjustment.

Third, in response to a cacophony of contradictory and confusing court decisions, as well as imprecise regulatory language, EMTALA's treatment of in-patients was addressed in the final rule. Under the Proposed Rule, EMTALA applied to unstabilized in-patients who were admitted through the ED, but not to those patients admitted on a scheduled basis. The problem with this language in perspective of hospital administrators and health care attorneys, was that it would be difficult to keep track of which patients to whom EMTALA applied. Now, however, in a rare display of regulatory common sense, all in-patients are to be treated the same. EMTALA's obligations end once the patient is admitted. Again, however, it is important to remember that patients are protected by Medicare's conditions of participation, as well as laws protecting against patient abandonment.

Fourth, in another long-awaited clarification, CMS has addressed the issue of EMTALA's application to call coverage. Under the proposed rule, call coverage was left extremely vague, requiring hospitals to act only in a way that "best meets the needs of the patient." Now, the standard has been modified to include language recognizing the hospital's resource limitations. Specifically, the standard requires that the hospital act in a way that "best meets the needs of patients who are receiving services required under EMTALA in accordance with the capability of the hospital, including the availability of on-call physicians."

Practically speaking, the Final Rule's revision has several effects. For one, hospitals are required, as a condition of Medicare participation, to maintain a list of physicians who agree to receive calls. These physicians are of course obligated to arrive in a timely manner if they are contacted while they are on-call. Failure to do so is likely to be deemed a violation of EMTALA. Two, EMTALA does not bind physicians to accept calls, which means that mandatory call coverage is not something that needs to be included as an aspect of every employment or services relationship. Moreover, physicians are not required to be on call at all times, and there is no "rule of 3," as some physicians had hoped. Finally, EMTALA specifically allows physicians to remain on simultaneous call, and allows them to perform surgery while on-call if a suitable back-up plan is in existence. The upshot of all of this, then, is that physicians should understand that they are obligated under EMTALA to respond to the hospital while on-call, if they have agreed to participate in the call rotation. Even if a physician has not agreed, he/she should always remember to act in accordance with his/her duties under state malpractice laws.

Fifth, the medical screening examination given must be consistent with the standard exams provided to the hospital's other patients who arrive at the hospital with similar symptoms. The exam must entail whatever medical procedure is reasonable to identify an EMC to the hospital of the symptoms displayed

by the patient.

Sixth, EMTALA contains a very specific definition as to exactly what constitutes an "emergency medical condition." An EMC is a "condition manifesting itself by acute symptoms of sufficient severity (including specific pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or their unborn child) in serious jeopardy, serious impairment to bodily functions or serious dysfunctions of any bodily organ or part." This definition is very important because if the MSE does not identify an EMC, the hospital has no further obligation. However, if the MSE identifies an EMC, the hospital is required to provide such additional treatment as may be necessary to stabilize the patient within the hospital's capability. If the hospital is unable to stabilize the patient, it is required to make an appropriate transfer to another medical facility as is required under the law. Once stabilization or the transfer has occurred, the hospital's obligations under EMTALA thereupon cease. You should be aware, though, that further obligations may exist under state law and Medicare's conditions of participation.

The stakes for violating EMTALA are very high, and include such things as costly fines and also exclusion from Medicare. That being the case, physicians are well served to peruse the regulations from time to time so that they have a competent understanding of the anti-patient dumping law. If you have any questions, we encourage you to contact your health care attorney.

IS THE OIG TARGETING GARDEN-VARIETY RECRUITMENT AGREEMENTS?

The use of recruitment agreements to attract physicians to hospitals and medical practices has been going on for a long time. These agreements, which generally involve the payment of some additional (beyond the compensation package offered in the employment contract) contractually-defined financial incentives to a doctor, offered for the purpose of attracting the physician to a community, present advantages to both employers and employees. From the employer's (typically a hospital) perspective, recruitment agreements offer a way to contract quality doctors to practice at their facility. Although certain hospitals, and medical facilities located in certain geographical areas, as a result of their well-known reputation of the inherent attractiveness of the community in which they are located, will always be able to recruit doctors relatively easily, however, facilities located in rural or impoverished parts of the country/state often find the task of acquiring new physician talent daunting. Payment of an additional subsidy through a recruitment agreement offers these facilities an invaluable means of bringing new doctors to their community healthcare facility. From the physician's point of view, these agreements are no less important; graduating doctors, often faced with heavy financial burdens, understandably find the additional compensation offered through a recruitment package highly attractive. Now, however, a recent indictment of an enormous health system, several of its component hospitals and its chief executive officer have cast an alarming shadow of doubt over the legality of certain, very common, recruitment arrangements.

THE CHARGES

The criminal indictment in question was issued on July 17, 2003 against Tenet HealthSystem Hospitals, Inc., Alvarado Hospital Medical Center, Inc., and Alvarado CEO Barry Weinbaum. The seventeen-count criminal indictment charged the defendants with one count of conspiring to violate the federal Anti-Kickback Statute, and sixteen-counts of offering and paying illegal remuneration in violation of that same law. The indictment alleged that the payment of over $10 million to fund approximately 100 physician relocation agreements was, in reality, a scheme to provide kickbacks to physician groups who recruited

new doctors and induced those physicians to refer patients back to Alvarado Hospital. For example, according to the indictment, four relocation agreements, pursuant to which, the recruited doctors joined the practice of Dr. Paul Ver Hoeve, were really nothing more than a way to compensate Dr. Ver Hoeve for inducing his newly acquired physicians to return business to the hospital. Indeed, Dr. Ver Hoeve allegedly received over $600,000 for his work in directing patient referrals back to Alvarado. Since the indictment was filed, Tenet has apparently undertaken efforts to improve compliance, and has expressed its determination to fight these charges in court.

THE LAW

Under the Anti-Kickback Law, it is a felony to knowingly and willfully offer, solicit, pay or receive anything of value, whether directly or indirectly, in exchange for or to induce the referral of items or services for which a federal healthcare program may make payment. Violations are punishable by criminal fines of up to $27,500.00 per offense, jail time of up to five years, or both. Additionally, violations of the Anti-Kickback Law may trigger exclusion from participation in the Medicare Program, civil monetary penalties of up to $50,000.00 per violation, plus treble damages. Although there is some dispute among courts on the degree of intent necessary to prove a violation of the Anti-Kickback Law, it is generally the case that at least one purpose of the action involved was to cause the prohibited action.

In recognition of both the commonality of, and the need for, arrangements to recruit physicians to rural or underprivileged areas or to healthcare facilities in medically underserved areas ("MUAs"), the Department of Health and Human Services ("DHHS") issued a safe harbor in 1999. The Practitioner Recruitment Safe Harbor allows compensation to be paid to physicians in healthcare professional shortage areas ("HPSAs") if the following conditions are satisfied: (1) Both parties sign a written agreement that specifies the obligations of each party and states the terms of any benefits they receive; (2) At least 75% of the revenue from the new practice comes from patients not previously seen by the practitioner at his/her old practice; (3) The benefits extend for no longer than three years and the terms of the benefits are not renegotiated during that three-year period (if the HPSA ceases to be designated as such during the three-year period, the terms of disbursement and benefits may not change); (4) The practitioner is not required to refer to, influence referrals to, or generate business for the entity as a condition of receiving benefits (the entity may require the practitioner to maintain staff privileges); (5) The practitioner remains free to establish staff privileges, refer to, or generate business for any other entity; (6) The value of the entity's benefits may never be based on the value/quantity of referrals or business generated for the entity by the practitioner and for which Medicare and Medicaid is billed; (7) The practitioner agrees to treat Medicare patients in a non-discriminatory manner; (8) At least 75% of the revenue of the new practice is from patients living in a HPSA or MUA or who are from a Medically Underserved Population ("MUP"); and (9) The payment and benefits may not reward any practitioner or entity (other than the practitioner being recruited) that might offer referrals to the recruiting entity.

Compliance with any of the Anti-Kickback Statute's safe harbors requires satisfaction of _all_ of the elements promulgated by DHHS with respect to that particular carve-out. As anyone who has dealt with fraud and abuse compliance in the past knows, satisfying all of the component elements to a safe harbor is often a very challenging, and sometimes quite impossible, task. Perhaps in recognition of the difficulty of meeting the various safe harbors, the Office of the Inspector General ("OIG") of the DHHS offers "advisory opinions" (opinions based on the legality of OIG's jurisdiction over certain arrangements) for the consumption of the public. These opinions are not legally binding for anyone other than the requesting party, although they are relied on frequently as a means of guidance by parties in similar factual situations.

The only advisory

opinion of with respect to physician recruitment packages was issued in May, 2001. Advisory opinion 01-04 held that the requesting hospital may recruit a doctor even though its offer of employment failed to satisfy two elements of the recruitment safe harbor: the hospital was not in a HPSA and the recruited physician's benefits would last longer than three years. In 01-04, the OIG noted that although the proposed arrangement could be read to constitute a violation of the Anti-Kickback law (assuming the requisite degree of intent was present), the particular situation at issue contained certain safeguards that minimized the risk of a violation, despite the fact that the textual elements of the recruitment safe harbor had not been met. Among these safeguards were the following: (1) the contractual commitment not to renegotiate the recruitment package during the agreement's terms; (2) the fact that the package was not conditioned upon or tied to patient referrals in any way; (3) the fact that the recruited physician was not prohibited from performing services at, or referring patients to, other hospitals; and (4) the fact that the hospital in question was located in a medically underserved area.

In the eyes of many industry observers, the Tenet indictment is extremely bothersome both because of the sheer size and scope of the stakes at issue and because, at least initially, there does not appear to be anything facially egregious with respect to the recruitment arrangements implemented by Tenet and Alvarado. In other words, while the factual allegations contained within the indictment are truly alarming, there is nothing facially wrong with the arrangements in principle, i.e., offering compensation to recruit physicians. What is more, although the arrangements at issue in Tenet may not have complied strictly with the requirements of the recruitment safe harbors, hospitals all across the country have long been engaged in the creation and implementation of arrangements that do not meet all of the exception's elements, relying instead on the protection afforded by the concert of (1) complying with as many elements of the safe harbor as possible; (2) the approval granted to non-complying arrangements, as evidenced by Advisory Opinion 01-04; and (3) the fact that it is difficult for federal prosecutors to meet the Anti-Kickback's standard of knowing violations and intent on the part of the individuals and entities involved to make payments in order to generate referrals. Thus, hospitals across America who have recruited physicians over the years through these agreements, as well as the physicians who have received payments as a recruitment bonus, feel less secure in recent days.

BUT WHAT DOES THIS ALL MEAN?

There are several important lessons that can be drawn from the Tenet indictment. A few of them are as follows:

First, hospitals, healthcare facilities, and doctors should be aware that any recruitment arrangements into which they might enter could very easily show up on the OIG's radar screen. The likelihood of this enhanced scrutiny is especially pronounced in non-rural and non-medically underserved areas. Generally speaking, the more attractive your location is geographically, the more likely it is that your recruitment arrangements will find their way to the desk of the federal regulator. For instance, it is a lot more reasonable to assume that hospitals located in Michigan's Upper Peninsula are going to have difficulty in recruiting doctors as opposed to facilities located in San Diego, California (where Alvarado is located). Thus, it is crucial that as many as possible, if not all, of the elements of the practitioner recruitment safe harbor be satisfied. While many of these elements can be met without undue difficulty (i.e., codifying the arrangement in writing; implementing a term of under three years; no prohibition against recruited physician from obtaining privileges at other facilities), others are more problematic. For instance, doctors must make sure that at least 75% of the revenue from the new practice comes from patients not previously seen and that at least 75% of this revenue comes from patients living in a HPSA or MUA, or who are from a MUP. If you have questions about the safe harbor, or you do not understand how to comply with its elements, we encourage you to contact your

healthcare attorney.

Second, as a doctor, you should be especially wary of recruitment packages by which a hospital offers you money to associate or affiliate with an existing medical practice. Although these arrangements are common, and while it is certainly true from the hospital's point of view that bringing new doctors into existing medical facilities is more financially and practically efficient than hiring them as stand-alone practitioners, however, there is a danger with inserting new doctors into existing practices. This is because the recruiting group will most likely have made referrals to the hospital in the past. In this situation, as is demonstrated by the Tenet indictment, there needs to be some coordination between the benefits provided to the doctor and the benefits afforded the group, which could, again, as shown by Tenet, be viewed as improperly benefiting from the group.

Third, physicians who are being recruited should be aware that even if their recruitment package passes under the Anti-Kickback Law, it may nevertheless prove illegal under other laws, most notably, the Stark Physician Self-Referral Law. While an in-depth discussion of Stark is beyond the scope of this article, the law generally prohibits physicians who have a financial interest in certain entities from referring Medicare or Medicaid patients to those entities for the furnishing of certain "designated health services" unless an exception to the law applies. More importantly, unlike the Anti-Kickback Law, Stark has no intent

element; if an arrangement is found to violate Stark, and no exception applies, a Stark violation will be found, regardless of whether the physician or hospital had any guilty intent. Thus, physicians who have pre-existing financial interests with hospitals that are attempting to recruit them should pay particular attention to this issue, and should consult an attorney if they are uncertain about exactly what Stark requires.

Finally, physicians should not be reluctant to present their concerns both to the hospital administrator and whichever representative of the group practice they feel is appropriate. These people have as much on the line as the medical professional does, and should be willing to discuss his/her concerns. If they are not willing to do so, or if they try to tell you that the Anti-Kickback law does not apply, their reaction should be treated with heightened skepticism.

WHAT IS NEXT?

Notwithstanding any ambiguity in this area, the one thing that is absolutely clear is that healthcare fraud issues are going to continue to be at the top of the OIG's agenda. The confluence of the facts that: (1) healthcare is the second-most heavily regulated industry in the U.S. today (only to nuclear power); and (2) healthcare fraud is the second-most lucrative source of income for federal fraud fighters (only to organized crime) means that extensive work exists for both the regulators and for those of us who are regulated.

NO MORE RURAL PROVIDER EXCEPTION?

Many of you who have read The Doctor's Chart in the past are probably familiar with the "Rural Provider Exception" to the federal Stark Physician Self-Referral Law (the "Stark Law"). Indeed, we would venture to say that many of the financial relationships in which you might be involved were entered into based on the reliance of this exception, or some other carve-out from the demanding and always frustrating Stark Law. Now, however, the highly controversial Medicare Prescription Drug Bill, presently being debated by a conference committee in Washington, stands ready to destroy this exception, and thus to place a veritable avalanche of physician-hospital relationships at risk of violating the law, regardless of the intent of the healthcare professionals involved.

THE BACKGROUND

The Stark Law basically prohibits two actions: (1) Physicians may not make a referral to an entity with which they or their immediate family members have a financial relationship for the furnishing of any of ten specifically defined designated health services; and (2) entities that provide designated health services may not bill Medicare, Medicaid, third party payers or any other individual, including the recipient of the service, for such referred services. Unlike the often-cited and similar in principal federal Anti-Kickback Law, a violation of which requires a modicum of guilty intent to be present, the Stark Law is a bright line statute: simply put, if you are in violation of Stark, you have violated the law regardless of whatever degree of intent you might posses. There are, however, a number of specific, highly technical exceptions to the Stark Law. Given the high stakes associated with the Stark Law and its pervasiveness in today's healthcare environment, the importance of these exceptions cannot be overemphasized.

STARK RURAL PROVIDER EXCEPTION

The applicability of a particular Stark exception will of course depend on the facts and circumstances at issue in each particular situation. One of the most commonly used Stark exceptions, the In-Office Ancillary Services Exception, requires, among other things, that all services provided take place in one central facility. Another common exception, the Physician Services Exception, requires that a practice qualify as a "group practice," as defined in the Stark Law, something that is not always easy to prove. Due to this type of complexity, providers are often forced to search the catalog of available exceptions in an effort to protect their business. For many providers in Wisconsin and Michigan, the Rural Providers Exception offers valuable recourse. Under this exception, physicians can refer Medicare- or Medicaid-designated health service patients to an entity in which they have a financial interest if the company providing the service furnishes "substantially all" of its designated health services to patients who live in a rural area. "Substantially all" is defined as at least 75% of the company's services, and "rural" is defined as outside of a Metropolitan Statistical Area (defined by the Executive Office of Management and Budget as one or more counties that contain a city of 50,000 or more inhabitants or an "urbanized area" as defined by the Census Bureau with at least 100,000 people) [42 CFR § 411.325(c)].

The discrepancy between the narrowness inherent in most of the Stark exceptions and the broad scope of the Rural Provider Exception offers ample demonstration of its value. Indeed, if one breaks down the precise language of this exception, it becomes clear that there are really only two key components: (1) the entity involved must provide at least 75% of its services to patients who live in (2) an area that is not defined as a Metropolitan Statistical Area. Due to their simplicity and objective nature, meeting these standards is not complex. Standard office recordkeeping is sufficient for determining whether or not 75% of the entity's services are provided to patients who live in a rural area. And, searching the

federal government's database at http://belize.hrsa.gov/newhpsa/newhpsa.cfm provides quick answers to the question of whether or not your geographical area meets the definition of Metropolitan Statistical Area. For your information, Wisconsin, Michigan and Minnesota have a large number of counties that qualify. The upshot of the Rural Providers Exception, then, is not only that meeting its terms allows physicians to enter into business arrangements that might otherwise run afoul of Stark, but also that, unlike the great majority of the exceptions to the Stark Law, satisfying the conditions of this exception is relatively straightforward. It is this combination of factors that has caused so many physicians and a number of other healthcare providers in Northern Wisconsin and Michigan's Upper Peninsula to rely on the Rural Providers Exception.

SO WHAT HAPPENED?

The danger to the Rural Providers Exception is buried deep in the confines of a seemingly unrelated piece of legislation, the Prescription Drug and Medicare Improvement Act of 2003 (S.1). This legislation, passed by the U.S. Senate on a bipartisan vote of 76 to 21, is designed primarily to add a prescription drug benefit to the Medicare Program. A bill similar in intent, though not in substance (H.R.1) passed the U.S. House of Representatives on June 27, on a substantially party-line vote of 216 to 215. The legislation that went to the conference committee, where it is still in the process of being debated (as of this edition of the Dr.'s Chart). Although there has been progress in reconciling some aspects of the competing bills, there has not, as of yet, been any progress in curing the damage caused to the Rural Provider Exception.

As things stand today, Section 453 of the Senate Prescription Drug Bill would "change" the Rural Provider Exception in such a manner as to effectively render it worthless. This is because the language contained in Section 453 of S.1 would make the Rural Provider Exception applicable only to services not otherwise available in rural areas. Moreover, the question of whether the services are otherwise available in these areas, according to the legislation, would need to be determined by DHHS. These changes to the Rural Provider Exception would essentially destroy its applicability because of the vagary of the language and because it is difficult to foresee too many rural areas where medical services are available absolutely nowhere therein. Under the revised Rural Provider Exception, for example, both Clark and Door counties, each of which would presently qualify for the exception due to their statuses as non-metropolitan areas, would no longer qualify as a result of the fact that at least two hospitals are located therein. Thus, any business arrangements that may have been formed in Clark County or Door County in reliance on the Rural Provider Exception would be suspect in the future. What is more, despite the fact that the revised Rural Provider Exception would not be retroactive, it would apply to referrals made for designated health services after January 1, 2004. In other words, while past business would remain protected, any future referrals that are deemed by this new definition, to no longer be protected by the Rural Provider Exception could subject you to liability under Stark.

IS THIS ALL SET IN STONE?

Thankfully, no. There are in fact at least two saving graces that may yet decide the issue. For one, the Rural Provider Exception (the original, not modified by S.1) was never finalized by DHHS. As you may recall, proposed regulations, refining the Stark II Law of 1995, were issued on January 9, 1998. These regulations were substantially revised and divided into two "phases," the first of which was issued in final form on January 4, 2001. These Final Phase 1 rules became effective in January, 2002. The Final Phase 2 rule, in which the Rural Provider Exception will be included, has not yet been released, despite repeated promises by CMS. Given the substantial revisions found in Phase 1 of

the rule, it is reasonable to assume that Phase 2 will see somewhat profound modifications as well. Thus, even if the revisions to the Rural Provider Exception found in S.1 ultimately become law, it is not unlikely that CMS will revisit the issue and revise the exception again.

Two, given the significant differences that exist between the House and the Senate's versions of the Prescription Drug Bill, as well as the fact that S.1 contains no similar provision, there is no guarantee that any bill will become law, much less one including this change to the Rural Provider Exception. This skepticism is underscored, moreover, by the fact that the federal government is presently faced with unprecedented fiscal problems. Vitiating the Rural Provider Exception, as 5.1 would do, unfortunately would not help the government's bottom-line.

WHAT SHOULD YOU DO?

The best thing for medical professionals to do going forward is to keep one eye trained on the House-Senate conference committee in charge of the future of the Prescription Drug Bill. Although neither of Wisconsin's senators or representatives actually sit on the committee, a number of powerful politicians are involved, including Senate Majority Leader, Bill Frist (R-TN) and Minority Leader, Tom Daschle (D-SD), as well as House Majority Leader, Tom Delay (R-TX) and Medicare aficionado and ranking member of the House Energy and Commerce Committee, John Dingell (D-MI). We encourage you to contact your senator or representative for updates as to the status of this important legislation. Additionally, the "Thomas" website, located at http://thomas.loc.gov, offers a comprehensive database, searchable in a variety of ways that can provide minute-by-minute updates as to the status of legislation in Congress. If you have any further questions, or if you are unable to receive an update through the ways described above, you should contact your healthcare attorney for an update on the status of the Rural Provider Exception.

THE PARADOX OF ACHIEVING QUALITY RELATED GOALS OF HEALTH CARE THROUGH CREDENTIALING DECISIONS

One of the "hotter" and increasingly more frequent topics discussed in health law is the issue of credentialing and de-credentialing. This article focuses specifically on the issues arising from both medical peer review boards and hospital policies of quality assurance. From the perspective of the hospital or the peer review board, this article will provide some guidance on how hospitals and members of the peer review board may avoid liability to physicians. Furthermore, this article will provide an extensive discussion about the various remedies that may be available to physicians whose rights have been violated due to a privileges decision.

The general rule upholds a hospital's standards relating to physicians' staff privileges where they are reasonably related to patient care, sufficiently well defined, and not arbitrary or capricious or susceptible to arbitrary or discriminatory application. In fact, the Health Care Quality Improvement Act (HCQIA), which does not provide a private cause of action, affords immunity from money damages to peer review committees that comply with certain standards. Generally, HCQIA provides immunity to any professional review action conducted "in the reasonable belief that the action was in furtherance of quality health care." However, courts may invalidate the application of arbitrary standards regarding hospital staff membership by either a public or a private hospital, as where the standards sought to be applied are unrelated to the hospital's purposes and operational needs and do not reasonably further a legitimate health-care objective. In addition, under WSA § 146.37 courts presume and grant civil immunity for all peer review actions taken in good faith. However, if individuals on the peer review board act with an improper motive they may be subject to personal liability. *See* Harris v. Bellin Memorial

Hospital, 13 F.3d 1082, 1087 (7th Cir. 1994) (Seventh Circuit stating specific facts demonstrating an improper motive can establish bad faith of individuals on peer review board). With these general principles in mind, this article will now analyze a few situations in which credentialing issues arise.

Often hospitals will enter into an exclusive contract with a group of physicians to fulfill all of their needs in a certain department. As a hospital has the right to treat professionals differently if there is a rational basis therefore, it may enter into a contract with certain physicians to render, exclusively, a particular service for a hospital, and on the basis of such contract deny to its staff to another practitioner of that specialty.

While the refusal of the governing body of a hospital to permit physicians professing a certain system of medicine to practice in the hospital has been upheld, class wide discrimination against a particular discipline or class of certification has been prohibited. Where an application for hospital privileges is not denied solely on the ground that the applicant is licensed as a particular practitioner contrary to statute, the hospital may require a physician to be certified in a narrower classification within a discipline

A hospital may require members of its medical staff to carry malpractice insurance particularly if it is authorized to do so by statute.

Hospitals often will require that a physician be board certified in a medical specialty, such as orthopedics or obstetrics, to obtain medical staff membership or clinical privileges. While courts have held that this is a legitimate goal in pursuit of quality health care, they have struck these provisions down when they are applied in an arbitrary or capricious manner. *See* Sokol v. Akron General Medical Center, 173 F.3d 1026, 1029 (6th Cir. 1999) ("Hospitals must provide procedural due process…in adopting and applying reasonable, nondiscriminatory criteria for the privilege of practicing surgery in the hospital").

While a hospital will generally be able to deny admission to its medical staff when a physician is applying to a closed department, they must do so in a uniform and consistent manner. If the hospital claims to have a closed staff, but subsequently allows the son of one of the top surgeons privileges, a court will find the policy arbitrary and capricious and will invalidate the hospitals' policy. *See* DeSai v. St. Barnabas Medical Center, 103 N.J. 79, 79 (N.J. 1986) (Invalidating hospital policy which claimed to be a closed staff hospital but granted privileges to physicians who had business relationships with physicians already on the medical staff).

When a hospital has acted in an arbitrary or capricious manner in the adoption or application of a privilege policy the physician has various remedies at their disposal. The most obvious remedy sought by physicians alleging wrongful revocation of staff privileges is an injunction ordering the hospital to grant privileges or to give a second review to the particular physician consistent with the courts' opinion. In addition, physicians receiving adverse decisions concerning privileges may bring many other common law tort and contract claims. See Clark v. Colombia/HCA Information Services, Inc., 23 P.3d 215, 219 (NV 2001) ("Courts will not stand idly by if peer review board actions are arbitrary or capricious, contravene public policy, or are contrary to state or federally mandated tort protections"). One common claim is the tortuous interference with physician's contract rights and prospective contractual relations with other parties.

Employment discrimination and racial discrimination are two of the newest theories being used by physicians who are denied medical staff privileges. Also, a growing theory argues that a physician who is denied privileges or staff membership may claim that he has been deprived of liberty or property without due process of law under the Fourteenth Amendment. Courts are still deciding whether sufficient state action exists to pursue a claim under the Fourteenth Amendment, but nonetheless, it is an argument currently being made by physicians. Furthermore, a hospital may violate antitrust laws if it denies medical staff membership for anti-competitive reasons. Typically, antitrust violations occur when a hospital uses the credentialing process as a means of restraining trade or eliminating competition. If the hospital's governing body has excluded a physician for anti-competitive reasons, the body may have violated the Sherman

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uses the credentialing process as a means of restaining trade or eliminating competition. If the hospital's governing body has excluded a physician for anti-competitive reasons, the body may have violated the Sherman Act and state antitrust laws. These violations potentially subject the hospital to costly litigation, treble damages, and civil or criminal penalties. Therefore, if a hospital denies privileges or medical staff membership for lack of board certification when its true intent was to eliminate competition or restrain trade, the hospital may have violated the Sherman Antitrust Act or state antitrust laws.

A hospital is granted a great deal of latitude in making quality of care decisions concerning who will be granted medical staff privileges at their facilities. When the hospital acts in an arbitrary or capricious manner, or acts pursuant to goals not in furtherance of quality health care objectives, they run afoul of the law. Physicians who are the victims of this conduct have various remedies at their disposal. These remedies range anywhere from breach of contract to federal discrimination claims. Physicians also can hold members of the peer review board responsible when they fail to act in good faith. Thus, it is necessary for all persons involved in peer review activities or credentialing decisions to know their duties and to act with the utmost care.

OUR NEWSLETTER is designed to provide you with highlights of recent health care issues. Because the articles are general in nature, we encourage you to contact your health law attorney for personal advice before you act.

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