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HEALTH LAW UPDATE

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BOCA RATON / FT. LAUDERDALE / MIAMI / ORLANDO / TALLAHASSEE / TAMPA / WEST PALM BEACH

Corporate Responsibility Reflected in Hospital Criminal Conviction

GABRIEL L. IMPERATO

A not-for-profit community hospital in Western Michigan was found criminally liable for fraudulent activity in a case which is a first of its kind involving corporate responsibility for hospital conduct, including the actions of its medical staff. The indictment, plea agreement and conviction of the hospital is clearly intended by the Federal government to convey the message that corporate health care providers will be held accountable for criminal and civil fraud in the health care industry. The conviction of United Memorial Hospital ("UMH") in Greenville, Michigan is perhaps only the first reflection of the effects of the Enron/Arthur Andersen case and the government's efforts to hold health care corporations,

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COVER STORY:

False Claims Act Liability Expanded and Contracted in Two Important Decisions

EDWARD HOPKINS AND GABRIEL L. IMPERATO

The United States Supreme Court and the United States Court of Appeals for the Fifth Circuit recently rendered important decisions construing the breath and scope of the application of the United States False Claims Act (FCA). The Supreme Court found that the FCA did indeed apply to cities, counties and other instrumentality's of government, such as public hospital districts, even though the Supreme Court had decided three years ago that the

FCA did not apply to the states in the case of *Vermont Agency for Natural Resource v. United States ex. Rel. Stevens*. The United States Court of Appeals for the Fifth Circuit in an en banc decision reversed a prior panel decision and found that there is a "materiality" requirement involving allegations of the submission of false claims and that FCA liability cannot be based on alleged contractual, regulatory and other statutory violations

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such as hospitals, responsible and accountable for fraud and abuse activity of its employees and agents.

The enforcement of the health care fraud and abuse laws against individuals and organizations is not novel in the health care industry, but the investigation, prosecution and conviction of corporate providers for crimes, whether they be hospitals or other health care facilities and/or profit or not-for-profit entities, is consistent with the Department of Justice's recently announced intentions to hold business organizations subject to criminal charges. (See Memorandum from Larry D. Thompson, Deputy Attorney General to the Department of Justice Components and the United States Attorneys re: "Principals of Federal Prosecution of Business Organizations," dated January 20, 2003).

The consequences of this increased emphasis on corporate accountability and its ramifications for the health care industry are no better reflected than in the circumstances surrounding the conviction of UMH. The key factual components of the basis for the conviction of the hospital clearly signal the end of those days when the Board of Directors and Officers of a hospital can afford to act in deliberate ignorance or deliberate disregard of the activities taking place within the corporate organization. This type of corporate accountability for hospitals has also recently been reflected in the announcements of Federal, criminal and civil fraud investigations involving a Tenet health care hospital in California and an HCA hospital in Florida, involving allegations related to the nature and utilization of medical procedures in the hospital's cardiac catheterization programs.

The salient facts in the UMH case are instructive and are as follows:

1. The hospital was governed by a Board of Trustees (Board), which characteristically had relied upon its medical staff, in particular the Medical Executive Committee (MEC) and the Professional Activities Committee (PAC), to oversee the practices of physicians who have privileges at UMH. The Board, which serves voluntarily, relied upon its administrative management team, particularly the CEO and the CFO, to manage the day-to-day operations of the hospital

2. The MEC and the PAC were accountable to the Board for making decisions about whether to grant, deny, restrict or suspend a physician's privileges and to generally review the physician's practices to ensure the quality of patient care.

3. The hospital was apparently struggling financially in the early '90's and it recruited an anesthesiologist to provide full-time anesthesia services for surgical procedures. This anesthesiologist apparently had no training or specialized experience in pain management, but commenced performing pain management procedures upon arrival at the hospital, which were in addition to the traditional anesthesia services. This doctor was also chairman of the anesthesia department at the hospital and apparently approved his own application expanding his clinical privileges, to include "management of problems and pain relief."

4. The number of surgical procedures performed by the anesthesiologist rose dramatically from 24 in January of 1994 to 230 in December of that same year. The number and pace for the procedures being performed by this doctor alarmed the operating room medical staff, a number of whom described the situation as an "assembly line" or "mill."

5. The record also reflected that beginning in late 1994 a management

team at the hospital began receiving complaints about the anesthesiologist from nurses, operating room staff and ultimately physicians on the medical staff at the hospital.

6. The nurses complaints were numerous and included allegations that the anesthesiologist performed repeated procedures on the same patients, even though the patient showed no improvement; that the anesthesiologist described himself to the medical staff as the "Sam Walton" of pain management; that he freely admitted he was at the hospital to make money and intended to double his "stats" every month; that he rewrote a poster to read "Quantity over Quality." The nurses also reported that the anesthesiologist often operated on "walk-in" patients, apparently without conducting a history and physical examination to even remotely determine whether the procedure was medically necessary.

7. These complaints were apparently submitted to supervising nurses who were advised by UMH Administration that the anesthesiologist was responsible for generating significant income for the hospital and that they should keep their concerns to themselves or leave the hospital.

8. There were also complaints expressed by physicians on the medical staff who also noted that the anesthesiologist repeated procedures on patients who were apparently not benefiting from those procedures. A physician on staff apparently recommended that the anesthesiologist not be given expanded pain management privileges.

9. There were apparently also complaints received from patients, one of which advised one of the doctors who was a member of the hospital's PAC that the anesthesiologist admitted doing procedures simply for purposes of increased reimbursement. There was no action

CORPORATE *continued from page 2*

taken by that particular doctor or the PAC to investigate this complaint.

10. The Board of the hospital was advised of these concerns about the anesthesiologist as early as May of 1995, but was advised by the CFO that the anesthesiologist's practice "had a favorable financial impact on hospital operations when compared to the budget." The Board, nevertheless, drafted a letter to the PAC directing it to examine the anesthesiologist's practice of using a dorsal column stimulator (a surgically implanted device designed to block pain) and to determine the appropriateness of this procedure at the hospital. The PAC never responded to the Board's inquiry and apparently took no further action.

11. The Chairman of the Board, at the same time as this examination, apparently stated at a board meeting that, while the hospital wanted to find someone to review the anesthesiologist's practices, it was important to ensure that it was not someone who would antagonize him or cause him to take his practice to a competitor. The CEO of the hospital had apparently stated during 1996 to a board member that the anesthesiologist's practice constituted approximately one-third of the hospital's income and that "we would not want to hurt him would we?" The revenue for the hospital from 1993 to 1994 increased by nearly \$2 million dollars, which is due in large part to income generated by the anesthesiologist's pain management practice.

12. The anesthesiologist apparently also formed joint venture financial relationships with two other doctors on the medical staff of the hospital, one of which was the Chief of Staff and the other who was the Chief of Emergency Medicine. These three physicians also incorporated "PCS Greenville" with the goal of negoti-

ating with the hospital to increase compensation from the hospital. These doctors continued to sit on committees responsible for reviewing and regulating the anesthesiologist's pain management practice, notwithstanding these mutual financial interests between the three doctors and the recommendation of at least one other doctor that the Chief of Staff and the Chief of Emergency Medicine recuse themselves from review of the anesthesiologist's practices because of a conflict of interest.

13. The proliferation of these complaints apparently had little or no impact on the management of the hospital which did virtually nothing to restrict the number or type of procedures the anesthesiologist was performing over the course of the time period in question and, instead, took actions to discourage complaints against the anesthesiologist. For example, one doctor who continued to voice concerns about the anesthesiologist's practice was told by the then CEO that his comments were not welcome. The same doctor saw his medical referrals dwindle after voicing these concerns and after noting the Chief of Staff and the Chief of Emergency Medicine's financial conflicts of interest regarding the anesthesiologist. The Chief of Staff, acting on behalf of the MEC, in fact, suspended the privileges of one of the doctors who had challenged the anesthesiologist's qualifications to perform continued procedures. Furthermore, the anesthesiologist complained to the then CEO about these doctor's complaints and the CEO shortly thereafter left the hospital to work for the anesthesiologist.

14. An outside medical expert was eventually retained by the hospital to review the medical necessity of the anesthesiologist's surgical procedures. This expert reported that he was unable to render such an opinion, given the lack of

medical documentation in the anesthesiologist's files. However, the PAC of the medical staff of the hospital took no action for eight months and when it did only counseled the anesthesiologist to improve the documentation of his work. The anesthesiologist, in fact, continued to perform pain management procedures at the hospital in an unrestricted fashion up until August of 1996 when he voluntarily resigned from the medical staff after meeting with the Board's attorney.

15. The Board eventually submitted eighty patient charts from the anesthesiologist's files to the Peer Review Organization of Michigan (PROM) after the death of one of the anesthesiologist's patients. The PROM issued a report in November of 1996 (three months after the anesthesiologist left the hospital), noting the following:

"There were several themes that were recurred in the records examined: Specifically, the evaluative process presented was uniformly inadequate. Results of the testing data, and findings either within history or on physical examination that supported the purported diagnostic impressions were consistently absent. There was an apparent routine over use of invasive techniques without clear indications. The Pain Management activities seemed to have proceeded without evidence or [Sic] efficacy, quality assurance or outcome evaluation...Continuing to allow invasive procedures without objective evidence of improvement in pain level, narcotic use, functional improvement or return to work is not warranted."

16. The hospital continued for several years after this report from the PROM to collect fees generated by the procedures performed by the anesthesiologist, including fees for services performed on the patient who died. There was no effort on the part of the hospital to quantify the

SPOTLIGHT:

Guidance on OIG Issues

LESTER J. PERLING

In March and April, 2003, the Office of Inspector General of the Department of Health and Human Services (OIG) issued an Alert, a Special Advisory Bulletin, and a Special Fraud Alert. In these documents the OIG address contractual joint ventures, durable medical equipment (DME) marketing, and using Medicare words and symbols improperly.

CONTRACTUAL JOINT VENTURES

In April, 2003, the OIG issued a Special Advisory Bulletin addressing what it called “certain complex contractual arrangements for the provision of items and services.” The OIG believes that contractual joint ventures are proliferating and that some of them are becoming more aggressive and may violate the federal anti-kick-back statute.

In the Bulletin, the OIG discusses contractual arrangements in which a healthcare provider in one line of business (the “Owner”) expands into a related health care business by contracting with an existing provider of the related item or service (the “Supplier”) to provide the new items or services to the Owner’s existing patient population. The Supplier not only manages the new line of business, but may supply it with products, employees and other services. The OIG is concerned about the Owner’s delegation of the entire operation of the related line of business to the Supplier, which would otherwise be a

potential competitor, and what it sees as the Owner’s receipt of the profits of the business as remuneration for its federal program referrals to the Supplier.

The OIG provides several examples of potentially problematic contractual relationships. The first of these examples involves a hospital that establishes a subsidiary to provide DME and enters into a contract with an existing DME company to operate the subsidiary and provide its inventory. The existing DME company already provides the same services as those provided by the hospital’s new subsidiary and bills for those services.

The second example involves a DME company that sells nebulizers to federal healthcare beneficiaries. Through a management contract, a mail order pharmacy runs the DME company’s pharmacy and also sells all nebulizer drugs to the DME company for its inventory. The OIG’s final example involves a group of nephrologists that establish a company to provide home dialysis supplies to their patients. The new company contracts with an existing supplier to operate the new company and provide all goods and services to it.

The OIG goes on to identify several aspects of a suspect contractual joint venture, which it identifies as not being an all inclusive list. The list includes:

- **New Line of Business** — The Owner typically seeks to expand into a healthcare services that can be provid-

ed to the Owner’s existing patients.

- **Captive Referral Base** — The newly-created business predominantly or exclusively serves the Owner’s existing patient base.

- **Little or No Bona Fide Business Risks** — The Owner’s primary contribution to the venture are referrals. It makes little or no financial or other investment in the business.

- **Status of the Supplier** — The Supplier is a would be competitor of the Owner’s new line of business and would normally compete for the captive referrals and has the capacity to provide identical services.

- **Scope of Service Provided by the Supplier** — The Supplier provides all or many of the key services necessary to operate the new business.

- **Remuneration** — The practical effect of the arrangement is to provide the Owner with the opportunity to bill for business that is otherwise provided by the Supplier.

- **Exclusivity** — The parties may agree to a non-compete clause, barring the owner from providing items of services to any patients other than those coming from his business or barring the supplier from providing services on its own rights to the Owner’s patients.

The OIG found that these types of arrangements exhibit five common elements:

- (1) The Owner expands into a related line of business dependent upon referrals generated by the

Owner's existing business, primarily serving the Owner's existing patient base.

(2) The Owner neither operates the new business itself nor commits substantial financial, capital or human resources to the venture, but contracts out all of the operations of the new business to the Supplier. All billing is done, however, in the name of the Owner.

(3) The Supplier is an established provider of the same service as the Owner's new line of business.

(4) The Owner and Supplier share the economic benefit of the Owner's new business. The Supplier takes its share in the form of payment under the contract with the Owner while the Owner receives its share in the form of residual profits.

(5) The aggregate payments to the Supplier vary with the volume or value of business generated by the Owner. The payment to the Supplier typically varies based on the number of goods and services provided, while the Owner's payment, the profit, also varies based on the Owner's referrals.

The OIG then explains why it believes that these types of relationships would not fall into a safe harbor if the federal anti-kickback statute. First, the supplier usually agrees to sell items and services to the Owner at a discounted price. Because this discount is given as part of "an overarching business arrangement," it does not qualify for protection under the discount safe harbor. The OIG believes that a discount is not based on arm's-length transaction when it is provided by a seller to a purchaser in connection with a common venture.

The second basis for the OIG taking the position that these contractual joint ventures cannot fit within a safe harbor is that "the illegal remuneration is often a difference between the money paid by the

Owner to the Supplier and the reimbursement received from the federal health care programs." The OIG believes that the Supplier is providing the Owner with the opportunity to generate a fee and a profit and that this is what constitutes the potentially illegal remuneration.

TELEMARKETING BY DURABLE MEDICAL EQUIPMENT SUPPLIERS

On March 3, 2003, the OIG issued a Special Fraud Alert reminding DME suppliers that the Social Security Act prohibits unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item. There are exceptions to this prohibition, the most important being when the beneficiary has provided written permission. The Act prohibits payments to a DME supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation. The OIG also contends that any such claims are false claims subjecting the supplier to potential criminal, civil, and administrative penalties.

The OIG asserts that many DME suppliers are using independent marketing firms to place unsolicited telephone calls to Medicare beneficiaries on behalf of the DME company. The OIG believes that suppliers cannot do indirectly, i.e., through an agent, what they are prohibited from doing directly. The OIG holds DME suppliers responsible for the acts of third parties with which it contracts.

MISUSE HHS WORDS SYMBOLS AND EMBLEMS

On April 3, 2003, the OIG served a demand letter on U.S. Seminar Corporation of La Mesa, California. The demand letter seeks civil monetary penalties of over \$1 million for the misuse of the word "Medicare" by the Company in its marketing practices and documents. The OIG believe that the marketing documents and practices could be construed

as conveying the false impression that the Company's seminars are approved, endorsed, or authorized by Medicare, which is not the case.

The Social Security Act prohibits the use of the word "Medicare" and certain other words, symbols, and emblems associated with the Medicare program or the Department of Health and Human Services (DHHS) in such a manner that the person using them either knew or should have known would convey, the false impression that a solicitation or other item was approved, endorsed, or authorized by Medicare or DHHS or that such person had some connection with, or authorization from DHHS. Persons who violate this provision are subject to civil monetary penalties of up to \$5,000 for each violation, which in the case of direct mailing consists of each piece of mail. Typically the OIG will try to resolve the matter informally through a cease and desist letter. If not acted upon, then this is followed by a demand letter and civil monetary penalties, as in the case of the Company.

CONCLUSION

The OIG rarely issues three communications to the Medicare supplier community in such close proximity to one another, possibly indicating a new level of aggressiveness and enforcement by the OIG. Consequently, Medicare suppliers should seek competent legal counsel before engaging in the type of activities and relationships addressed by the OIG in these communications.

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FALSE CLAIMS *continued from cover*

if, in fact, such certifications were not material to the decision by the government to pay claims submitted for reimbursement.

The Supreme Court decision in *Vermont v. Stevens*, which was decided in 2000, held that states are not “persons” within the meaning of the FCA and thereby enjoy immunity from FCA liability. This decision created uncertainty about the application of immunity from FCA liability to counties, cities and other public entities, such as public hospitals and whether these governmental entities were “persons” under the FCA. The decision in the *Cook County v. Chandler* case, however, slammed the door on local governments which aspired themselves to be “non persons” under the FCA, thereby avoiding treble damages and penalties.

The Supreme Court in its Cook County decision also stated that the FCA’s multiple damages provision had both a compensatory, but also a punitive function, and that, in fact, once a private whistleblower was paid his or her share of the proceeds of potentially up to thirty percent of any recovery by the government, that the government would then net roughly double damages in any event which was an amount more consistent with the FCA’s remedial, as opposed to its punitive purposes. This dictum is important in that it reflects the Supreme Court’s explicit conclusion that an amount of damages in excess of double damages, plus any penalties would likely be punitive in nature. This, of course, would be important in assessing any damages under the FCA and ensuring that such damages are not unconstitutionally excessive and punitive (as opposed to remedial) in nature.

The Court of Appeals’ decision in the Southland case is also important for a number of reasons, but the most important is its implications for the ability of relators and relators’ counsel and the government to extract FCA settlements in cases that are based on alleged violations of other laws and contract terms, particularly where the contract or regulation at issue contains a separate enforcement or resolution methodology under the law.

The Southland case involved the submission to HUD of allegedly false certifications that certain subsidized housing was “decent, safe, and sanitary” (which of course is analogous to the certification on cost reports that a health care

provider was in compliance with all rules and regulations governing the Medicare and Medicaid programs). This certification was contained in a voucher submit-

ted to HUD in order to receive housing subsidies. The evidence demonstrated that HUD paid the claims, despite the false certification, because of its policy to allow property managers to use the funds to improve property and to avoid displacing tenants who depended on subsidized housing. The District Court in the case, in essence, found that the alleged false certifications were not, as a matter of fact, material to the decision by HUD to pay claims. This decision was reversed by a panel in the Fifth Circuit in a sharply divided opinion, but the panel decision was later vacated in an en banc rehearing proceeding. The en banc court held that whether a claim

is a “false claim” for FCA purposes “depends on the contract, regulation, or statute that supposedly warrants it.” The en banc court looked at the contractual agreement between the defendants and HUD and held that, “the owners were entitled to the housing assistance payments sought, and thus, they made no false claims.”

This decision has important implications for the alleged submission of false claims in the health care industry, particularly when it is based on a failure to comply with other rules and regulations of Federal health care programs, contractual relationships or other statutory violations, especially where there is an existing scheme for resolution of these

issues. This decision does not obviate the compelling dynamic between a claim for payment and the nexus to a basis for payment, however, it does underscore

**THIS DECISION
HAS IMPORTANT
IMPLICATIONS FOR THE
ALLEGED SUBMISSION
OF FALSE CLAIMS IN THE
HEALTH CARE INDUSTRY**

that there can be no liability under the FCA for a false statement unless it is used to get a false claim paid. The case also suggests that if there is an enforcement mechanism to terminate funding, then the government must follow that mechanism before claiming a violation of the FCA. This would, of course, be analogous to the various administrative mechanisms under the Medicare and Medicaid programs (i.e. pre-payment review, recoupment and suspension of payments), which are available to control funding or cut off funding under the Federal health programs. The case also highlights the court’s concern that any analysis under the FCA considers the

FALSE CLAIMS *continued from page 7*

language and application of any underlying contract, regulation or statute, as well as the course of conduct between the government and the alleged defendant to determine whether in fact a material false claim was submitted.

These two cases are important developments in FCA liability where in one case liability is explicitly expanded to include cities, counties and other public entities as "persons" under the FCA. The Fifth Circuit decision, however, clearly acts to restrict liability unless there is a showing of materiality and a course of conduct between the government and defendant which reflects that a false claim was in fact submitted to the government.

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**BC****CORPORATE** *continued from page 3*

extent to which the medically unnecessary procedures resulted in the receipt of unauthorized revenue from Federal health programs and/or third-party commercial payors, let alone return of such overpayments.

The developments in this case are likely a harbinger of things to come as corporate responsibility and accountability assert their place even more profoundly in the health care industry. The underlying basis for commission of a corporate crime is, of course, imbedded in the collective and aggregate activities of individuals who are representatives and agents of the corporation. The hospital was not the only party convicted of a crime in this case. The case also included conviction of the Chief of Staff and the Chief of Emergency Medicine on state misdemeanor charges of aiding and abetting larceny. The anesthesiologist was convicted of thirty three counts of mail fraud after a two week trial, including allegations of the performance of unnecessary procedures at UMH. The former CEO at the hospital is facing charges in a related case, including three counts of perjury before the Grand Jury concerning his involvement with contractual negotiations between the hospital and the anesthesiologist.

The conviction of the hospital of a crime raised the issue of whether or not it would be subject to mandatory exclusion from Federal health programs. The United States Attorney's press release on the case, in fact, stated that if the hospital were to have been convicted at trial, it would have been subject to mandatory exclusion from the Medicare and Medicaid programs. The hospital's plea agreement includes a stipulation

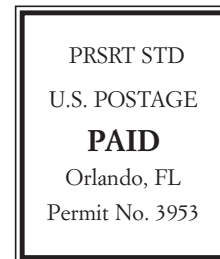
that the plea will be suspended by the court while the hospital serves a three year probationary period during which time it will be subject to an obligation to implement a compliance program designed to ensure that it will comply with all Federal and state laws and that its coding and billing practices will be audited on an annual basis. This type of sentence ordinarily would not, by itself, fall outside the definition of "conviction" for purposes of application of the mandatory exclusion authority under Federal health care programs. However, the plea agreement to a count of wire fraud against private payor programs may not fit into one of the categories for mandatory exclusion, which only relate to convictions involving Federal health care programs (Medicare and Medicaid) related crimes; convictions involving abuse and neglect of a patient; convictions involving controlled substances and convictions involving financial misconduct in other Federal health programs. Furthermore, the Office of Inspector General of Health and Human Services ordinarily does not impose mandatory exclusion as a practical matter until after sentencing in a case. The sentence in this case has not been entered and will not be entered (and in fact the case will be dismissed) as long as the hospital successfully completes the three-year probationary terms under the plea agreement.

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Captive Insurance – A Medical Malpractice Alternative?

MIKE SEGAL

Florida's medical malpractice insurance crisis (which also exists in many other States) continues unabated. As of this writing, and despite the urging of Governor Bush, the Florida Legislature has not passed a tort reform law. In fact, even if such a law was enacted, it is debatable how much malpractice premiums would be reduced, and when that reduction would begin. Carriers insuring physicians in Florida remain sparse, and costs continue to skyrocket.

If physicians want to remain insured (more than ever before, physicians are choosing not to be insured at all, which is called going "bare") but are unable to find insurance at an affordable price, what can they do? One alternative that is being closely examined by many physicians is owning their own insurance company. This type of insurance company is called a "captive" because it is owned by the insureds.

Captives can be based inside or outside the United States. Some U.S. jurisdictions, such as Vermont, encourage the formation of captives. Outside the U.S., the major captive locations have historically been Bermuda and the Cayman Islands, but recently several other islands, such as Barbados and Belize, have entered the picture.

If the group to be insured is too small (many advisors suggest that a minimum of \$750,000 to \$1 million in premiums are necessary to operate a private captive), there is another possibility - a "rent-a-captive" or cell captive. In this scenario, the physicians form a cell within an already-existing captive insurance company. This can be structured so that the monies, and liabilities, of the cell are not co-mingled with other cells or the base captive.

When a medical group owns a captive, and operates it successfully, the net earnings of the captive become assets of the group, instead of flowing to an unrelated company. Some physicians who have successfully operated captives have been able to pay dividends to themselves. Others have invested and ultimately obtained their share of the captive's earnings as a form of retirement plan.

Another alternative is a risk retention group (RRG). A RRG is an insurance company created under the Federal Liability Risk Retention Act of 1981. The Act allows a homogeneous group of businesses to write liability coverage while avoiding cumbersome multi-state licensing laws. Most RRGs are formed as captives and must be

domiciled in the U.S..

Forming a captive is not for everyone. It operates under the same fundamentals as a traditional insurance company. Thus, just like with traditional insurance, the premiums paid plus earnings must exceed claims paid plus operating expenses. High risk physicians, or physicians in high risk specialties, will probably not find a captive an inviting proposition. There are considerable costs — the costs of formation, annual management, actuarial charges, and reinsurance. Operating a captive is a real business.

Captive insurance has been around for a long time. Numerous hospitals have been insured through captives for many years. Many physician groups are now examining this alternative. You may want to do so too.

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