Hospital-Physician Transaction Compliance Strategies to Address Recent Fraud and Abuse Enforcement Actions

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Mr. Dowell would like to acknowledge the valuable assistance of Carol D. Scott, a health care law partner with the law firm of Hinshaw & Culbertson, Los Angeles, in the preparation of this article.

Notable Cases Illustrate the Importance of Establishing Fair Market Value and Documenting Commercial Reasonableness

Michael A. Dowell

Under the Obama Administration, the federal government has increased its regulatory efforts related to investigating and prosecuting health care fraud. The federal government has recently won judgments or entered into settlement agreements with numerous hospitals, health systems, and providers who are alleged to have violated the anti-kickback statute (AKS), the Stark law, and the False Claims Act as a result of prohibited hospital-physician transactions. Over the last five years, the number of new False Claims Act lawsuits filed by whistleblowers has nearly doubled.[1]

The consequences for hospitals and physicians can be severe, with civil enforcement action fines and penalties so high that the health care organization could be forced to file bankruptcy or cease operations. Criminal enforcement actions may lead to imprisonment, fines, restitution, and exclusion for participation in Medicare, Medicaid, or other state programs. The Affordable Care Act revised the federal AKS to facilitate easier enforcement and specifically provides that a violation of the AKS or Stark law constitutes a false or fraudulent claim under the False Claims Act.[2] The aggressive regulatory focus and close scrutiny of hospital-physician transactions warrants diligent action by hospitals and physicians and requires an understanding of how fraud and abuse laws apply to hospital-physician transactions.

The health care industry has recently experienced significant consolidation of hospitals and physicians.[3] It is important that hospital-physician transactions

are structured in a manner that does not violate the federal AKS or the federal Self-Referral Prohibition law (the "Stark law"). The conclusions and recommendations contained in this article are provided to assist hospitals and physicians in analyzing and evaluating their current hospital-physician transactions for physician employment contracts, medical director agreements, office space rentals, and similar arrangements[4] and to present a number of lessons learned from recent cases and compliance program best practices that may be used to achieve compliance with applicable law.

Laws and Regulations Applicable to Hospital Physician Transactions

Federal Anti-Kickback Statute

The AKS prohibits offering, paying, soliciting, or receiving any remuneration in return for referring patients or purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or in return for ordering any good, facility, item, or service paid for by a federally funded health care program.[5] Remuneration has been broadly defined to encompass anything of value.

The AKS is intent based, which means that a violation cannot occur unless the parties possess the requisite level of intent. Violation of the AKS is punishable by fines up to $25,000, imprisonment up to five years, or both.[6] Violators are also subject to exclusion from all federal health care programs, civil monetary penalties up to $50,000 for each violation, and assessments up to treble the amount of remuneration offered, paid, solicited, or received.[7]

The AKS has certain statutory exceptions and regulatory safe harbors. If the requirements of those exceptions or safe harbors are met, the arrangement is not subject to criminal prosecution. However, failure to meet all of the requirements of a particular, applicable safe harbor does not make the conduct illegal but rather subjects such conduct to review and analysis by the Office of Inspector General (OIG) on a case-by-case basis as to whether a party has the requisite knowledge and intent to support a violation.[8] A summary of the exceptions and safe harbors applicable to physician employment, medical office leases, and medical director contracts are set forth below.

Physician Employment Arrangements

The AKS includes a statutory exception for employment arrangements, which provides that monies paid by an employer to an employee for "covered items or services" does not constitute illegal remuneration under the statute as long as there is a bona fide employment relationship between the employer and the employee.[9] An AKS regulatory safe harbor similarly indicates that "remuneration" does not include such amounts paid to employees.[10] The OIG has interpreted the employment safe harbor to apply only to payments to employees for the provision of covered goods and services and has opined that payments compensating employees for the referral of patients would not be covered by the employee exception.[11]

Medical Office Lease Arrangements

The AKS also provides a safe harbor for space leases.[12] In general, payments made by a lessee to a lessor for the use of premises or equipment will be covered under the safe harbor exception, provided the following factors are met:

(i) the lease is set out in writing by the parties and specifies the premises or equipment covered;

(ii) the space or equipment does not exceed that which is reasonable and necessary for the legitimate purposes of the lease and is used exclusively by the lessee;

(iii) the lease is for a term of at least one year;

(iv) part-time leases for periodic intervals of time must specify exactly

the schedule and exact rent of the intervals;

(v) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and

(vi) the lease would be commercially reasonable if no referrals were made between the parties.

A lessee is permitted a holdover not to exceed six months, so long as the lease payment terms remain the same.[13]

Medical Director Contracts

Contracts for the performance of medical director services pose AKS concerns if the party performing the services for a hospital or health system is in a position to refer business to that entity and payments are made in a way that at least one purpose of the arrangement is to induce referrals. The AKS has a safe harbor for medical director arrangements. To meet the safe harbor, the medical director agreement must:

(i) be in writing, be signed by the parties, and specify the services covered by the arrangement;

(ii) if the agreement is for periodic, sporadic, or part-time work, the agreement must specify exactly the schedule of intervals in which services will be performed, the length of such intervals, and the applicable charges;

(iii) be for a term of at least one year (if terminated during the first year, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement);

(iv) cover all services the physician or immediate family member will furnish to the hospital (requirement is met if separate arrangements between the entity and the physician or any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally);

(v) contract for aggregate services that do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;

(vi) be for services that do not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law; and

(vii) the aggregate compensation must be set in advance,[14] be consistent with fair market value (FMV), and, except in the case of a physician incentive plan, not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.[15]

Federal Stark Self-Referral Prohibition Law

A second federal law that is applicable to hospital-physician transactions is the federal Stark law, which prohibits a physician from making referrals for Medicare-covered designated health services[16] (DHS) to an entity with which the physician or an immediate family member has a "financial relationship."[17] "Financial relationship" is defined as "a direct or indirect ownership or investment interest" or "a direct or indirect transaction."[18] In addition, an entity may not bill a patient, the Medicare program, or anyone else for services rendered pursuant to a prohibited referral.[19]

An entity that receives payment for DHS furnished pursuant to a prohibited referral must refund the payment within 60 days or otherwise will be subject to exclusion from all federal health care programs, as well as sanctions up to treble the amount of illegal remuneration and civil monetary penalties up to $15,000 per DHS.[20] Stark law violations also may form the basis for civil liability under the False Claims Act.[21] The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. A summary

of the Stark law exceptions applicable to physician employment, medical office lease, and medical director contracts is set forth below.

Physician Employment Arrangements

The physician employee exception to the Stark law requires that compensation: (i) is fair market value, (ii) does not take into account the volume or value of referrals by the physician, and (iii) is commercially reasonable.[22] The OIG has clarified that productivity bonuses may be paid to employed physicians for personally performed services, including services that constitute DHS. The physician's employment must be for identifiable services; thus, a job description detailing the services provided is a minimum requirement in the absence of an employment contract. It is important to note that the Stark law exception for employment relationships is much narrower than the AKS safe harbor for employees and provides that "remuneration" does not include any compensation paid by an employer to an employee, who has a bona fide employment relationship with the employer.

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Medical Office Lease Arrangements

The Stark law provides an exception for office space leases. The exception provides as follows: payments made by a lessee to a lessor for the use of premises will be covered under the statutory exception, provided the following factors are met:

(i) the lease is set out in writing by the parties and specifies the premises or equipment covered;
(ii) the space does not exceed that which is reasonable and necessary for the legitimate purposes of the lease and is used exclusively by the lessee;
(iii) the lease is for a term of at least one year;
(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and
(v) the lease would be commercially reasonable if no referrals were made between the parties.

A lessee is permitted a holdover not to exceed six months, so long as the lease payment terms remain the same.

Medical Director Contracts

The Stark law also provides an exception for personal services contracts. A medical director arrangement must be tailored to fit within the personal services exception to the Stark law, which provides as follows:

(i) the arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement;
(ii) the arrangement covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity;
(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
(iv) the term of the arrangement is for at least one year;
(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
(vi) the services to be furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
(vii) a holdover personal service arrangement for up to six months following the expiration of an agreement that meets the requirements in items 1-6 above is permissible, provided that such arrangement is on the same

terms and conditions as the immediately preceding agreement.[23]

Federal False Claims Act

Hospital-physician transactions that create Stark law or AKS violations can also create False Claims Act liability.[24] For example, in *United States ex rel. Repko v. Guthrie Clinic, P.C.*,[25] a federal court agreed that "every claim that defendant Hospital submitted to the government for payment" was false as a "result of [prohibited] referrals from physicians employed by [the] clinic."[26] The False Claims Act (FCA)[27] prohibits false or fraudulent claims for payment to the federal government. Under the FCA, liability attaches to a "false or fraudulent claim for payment" or a "false record or statement [made] material to a false or fraudulent claim."[28]

The *qui tam* provisions of the FCA allow a private citizen (called a relator) to bring a civil claim under the statute "for the person and for the United States Government … in the name of the Government."[29] When a claim submitted to Medicare or Medicaid has resulted from a kickback or is made in violation of the Stark law, it may be determined to be "false or fraudulent" creating liability for up to three times the amount of the claim plus a per claim penalty between $5,500 and $11,000.[30] Stark law and AKS violations have been successfully used by the government as the basis to establish a false claims case.[31] This combination allows the government to claim additional damages and makes provider compliance a requirement to continue ongoing operations.[32]

Key Legal Issues for Hospital-Physician Transaction Analysis

Fair Market Value

Fair market value is an explicit requirement of 10 Stark law exceptions[33] and three AKS safe harbors.[34] Although the AKS does not define "fair market value," the federal Stark law regulations define the term "fair market value" as the value in arm's length transactions, consistent with general market value.[35] Those same regulations define "general market value" as the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the agreement.[36] Generally, the fair market price is the price or compensation that has been included in bona fide service arrangements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.[37]

For purposes of determining fair market value for leases and office space rental and for the Stark law space rental safe harbor, "fair market value" means the value of the rental property for general commercial purposes. The Stark law office space rental exception and AKS safe harbor each require that, when determining fair market value, the value not be adjusted to reflect the additional value that one party would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under a federal health care program.[38]

Fair market value for the purpose of determining compensation for a physician employment arrangement or medical director agreement is usually determined by following CMS guidance, which indicates that:

> [A]n hourly payment for a physician's personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established

using either of the following methodologies: (1) the hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market; or (2) the hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least four of the following surveys and dividing by 2,000 hours: Sullivan, Cotter & Associates, Inc.—Physician Compensation and Productivity Survey; Hay Group—Physicians Compensation Survey; Hospital and Healthcare Compensation Services—Physician Salary Survey Report; Medical Group Management Association—Physician Compensation and Productivity Survey; ECS Watson Wyatt—Hospital and Health Care Management Compensation Report; and William M. Mercer—Integrated Health Networks Compensation Survey.[39]

Complex physician transactions may require analysis by an independent qualified third party, such as an accounting firm or professional appraisal firm that prepares a report detailing the methodology used in computing fair market value.[40]

One of the few cases analyzing the concept of fair market value and commercial reasonableness within the context of both the AKS and the Stark law in a lease transaction is the case of *Goodstein v. McLaren Regional Medical Center*. The *Goodstein* court concluded that a leasing arrangement did not violate either the Stark law or the AKS because the payments were part of an arm's length transaction, was set at fair market value, and did not reflect the volume or value of the physician's referrals.

In upholding the lease, the court focused on whether or not the lease payments were fair market value. The factors used by the court to assess fair market value included:

(i) the length and scope of the negotiations;
(ii) how the space was measured for calculating rental payments;
(iii) whether common areas were included in the arrangement;
(iv) the nature and quality of the facilities and amenities included;
(v) the term of the lease;
(vi) whether rent was paid during renovations;
(vii) a comparison of a "gross" versus a "triple net" lease;
(viii) the termination provisions of the lease;
(ix) non-competition and exclusivity provisions;
(x) rental rates for similar facilities in the relevant market;
(xi) appraisals performed prior to litigation; and
(xii) the consistency of each expert's appraisals.

Compensation May Not Be Based on the Volume or Value of Referrals or other Business Generated by the Referring Physician

All but one of the Stark law exceptions and all three of the AKS safe harbors that include a fair market value requirement also provide that compensation may not be based on the volume or value of referrals or other business generated between the parties. Services that are personally performed by the physician are not "referrals,"[41] and therefore a physician may be paid in a manner that directly correlates to his or her own labor (*e.g.*, the professional component of charges).[42] However, to satisfy the Stark law bona fide employee exception, a physician generally cannot be paid based on his or her referrals for DHS performed by others.[43]

It is important to note that the AKS safe harbor for employees does not include

the fair market value requirement or the prohibition on a relationship to the volume or value of referrals. Thus, a physician employee generally may be paid based on a salary; per unit of time (*e.g.*, per hour, day, or week);[44] per unit of service personally performed by the physician (*e.g.*, per relative value unit (RVU), patient encounter, or fee schedule); a percentage of charges or collections for services personally performed by the physician; or any combination of these.[45] In addition, a physician may be paid a bonus based on the physician's personal productivity[46] or the achievement of specified quality indicators.[47]

Finally, a physician may be paid for the physician's own labor in supervising others.[48] However, unless the physician is in a group practice, he or she cannot be paid an amount for, or percentage of, services performed by others or share in the overall profits of a facility or department.[49]

At least one court has analyzed whether or not compensation was based on the volume or value of referrals or other business generated by the referring physician. In *U.S. ex rel. Singh v. Bradford Regional Medical Center*,[50] a cardiology practice entered into an arrangement with Bradford Regional Medical Center under which Bradford would sublease a nuclear imaging camera used to perform diagnostic tests that are DHS. As part of the sublease, the physicians entered into a covenant not to compete with the provision of nuclear cardiology services by Bradford for the term of the sublease agreement.

Under the sublease, Bradford made a fixed monthly payment for the sublease of the equipment and an additional flat monthly fee for a non-competition agreement. The non-compete fee was calculated by an independent accountant, who determined Bradford's expected revenue with and without the sublease in place. The court held that the arrangement violated the Stark law, finding that the compensation was not fair market value — despite the fact that compensation was set at a flat fee.

Although there was no explicit requirement that the physicians refer their own patients to Bradford for tests, the court concluded that the non-compete agreements made it clear that the parties anticipated such referrals would be made and therefore the sublease rate was determined by taking into account the anticipated referrals from the physicians. Therefore, the court concluded that the transaction between the hospital and physicians for the equipment sublease was not fair market value.[51]

Commercial Reasonableness

Commercial reasonableness is an explicit requirement of eight of the 10 Stark law exceptions that contain the fair market value requirement and all three of the AKS safe harbors that contain the fair market value requirement.[52] The test for commercial reasonableness is distinct from that of the standard for fair market value. Fair market value looks at the *reasonableness of the compensation paid for a service*, and commercial reasonableness looks to the *reasonableness of the business arrangement generally*.[53]

CMS has indicated that an arrangement is "commercially reasonable" under the Stark law if the arrangement would make commercial sense if entered into by a reasonable health care provider entity of similar type and size and a reasonable physician (or group thereof) of similar scope and specialty, even if there were no potential business referrals.[54] Commercial reasonableness analysis should include review of the proposed arrangement from the perspective of strategic, operational or financial business purpose, and economic sense, taking into account whether or not the nature and scope of the transaction furthers the strategic, operational, or financial business objectives of the health care provider. Whether a transaction is commercially reasonable requires a look into the underlying economics of a transaction without taking into account the potential for referrals between the parties.

Determining commercial reasonableness of compensation in physician employment contracts requires evaluation of all factors of the employment arrangement. Important elements of an employment contract include term or length of the contract; renewal and termination provisions; full-time or part-time status; compensation methodology; administrative versus clinical time; set work hours; exclusivity; employee benefits; payment of business/travel expenses; supervision of assistants; physician training/qualification requirements; and realization of profit or loss.[55] Commercial reasonableness mandates that total physician compensation for physician services must be reasonable for the geographic market and physician specialty; documentation that the services for which the physician is being employed are reasonable and necessary; and the use of compensation studies to determine base salary, bonus, fringe benefits, and deferred compensation.[56]

Determining commercial reasonableness in medical office space lease arrangements should include review of the need for the office space, whether or not there is a lower cost alternative to a referral source, and confirmation that the medical office space contracted for does not exceed that which is reasonably necessary for the legitimate business purposes of the arrangement. To be commercially reasonable, real estate lease rates should cover the amortized cost of the building, interest, expenses, and a reasonable rate of return.

Commercial reasonableness factors to be used in the evaluation of medical director agreements include scope of duties, requirements for documentation (administrative versus clinical time and amount of time expended), verification of work performed; duplication of medical staff requirements; multiple agreements for the same directorship, term and termination provisions, and documentation that the physician has the training, skills and experience to perform the service.[57]

The significance of fair market value and commercial reasonableness to medical director agreements may be found in the report of the government's expert in *U.S. v. SCCI Hospital Houston*.[58] This *qui tam* case (eventually settled by the parties) involved the issues of fair market value and commercial reasonableness of the compensation paid by the hospital to three physician medical directors.[59] The government alleged that the hospital and three physicians submitted or caused the submission of false and fraudulent claims, false statements, and cost reports in order to obtain Medicare program payments. The court described the false claims, false statements, and cost reports as a prohibited arrangement implemented by the hospital to obtain business by using sham medical directorships to disguise illegal payments with sham medical directorships.

According to the government, the medical director agreements specified the duties to be performed by the physicians, but payment was made to the medical directors regardless of the duties performed, and even when no duties were performed. The three physicians performed little or no work in their capacity as medical directors and generally failed to document the few services they did provide.[60]

The government's valuation expert witness analysis of fair market value assumed the medical director services were valued on the basis of time spent performing duties multiplied by a commercially reasonable hourly rate of pay. The expert noted that hospitals usually require time records that report time spent on medical director functions or evaluate time expended by reviewing a medical director's work product and other evidence of performance, such as committee meeting minutes, teaching and training materials, institutional planning reports, recommendations made, professional reports, and presentations developed.

The expert explained that hourly pay rates are best determined by comparing

rates paid in similar situations or by using compensation rates from available industry data. The expert concluded that the medical director fees did not reflect fair market value and noted that there was no evidence of independent fair market valuations, no documentation of efforts to search the local market for amounts paid in comparable agreements and circumstances, and the hourly rates of pay were routinely higher than industry norms.[61]

The expert opined that the commercial reasonableness of a medical director agreement depended on the services being essential to the functions and operations of the hospital, based on an assessment of the duties performed by the medical directors.[62] The expert concluded that the medical director services were not required in the quantity contracted for (based on the size of the facility and nature of its operations), the services were not always provided, and hospital management did not oversee or assess each medical director's performance.[63]

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Recent Enforcement Actions Related to Physician Employment Contracts

Tuomey Healthcare System — Unreasonable Physician Employee Compensation

Tuomey Healthcare System operates Tuomey Regional Medical Center, a 301-bed hospital located in a medically underserved and health professional shortage area in Sumter, South Carolina, which has a population of approximately 106,000. On September 30, 2013, the District Court of South Carolina ordered Tuomey to pay $237.5 million for violating the False Claims Act and the Stark law.[64] The judgment is pursuant to a verdict from May 2013 in which a jury concluded that the physicians were paid in excess of fair market value, the overall benefits provided exceeded fair market value, and the terms of the agreement were not commercially reasonable because they took into account the volume or value of the referrals or other business generated between the physician and Tuomey.

Tuomey entered into part-time employment contracts with 18 specialist physicians which required the physicians to perform outpatient procedures exclusively at Tuomey, purportedly to discourage the physicians from moving their outpatient surgeries from the hospital's ambulatory surgery center to other locations, some of which would be owned by the specialist physicians. The employment contracts included the following terms: part-time employment with no set hours for service and covering only outpatient procedures; all outpatient procedures had to be performed at Tuomey facilities; base salary based on the previous year's collections; productivity bonus of 80 percent of collections; incentive bonus of up to 7 percent of productivity bonus; all malpractice premiums (including premiums covering the physicians for private office services and inpatient procedures) were paid by Tuomey; reimbursements for continuing medical education, periodicals/journals, and cell phones; and a 10-year term with a non-compete clause extending two years beyond the end of the contract.

The *Tuomey* court concluded that the physician compensation exceeded fair market value because comparison data from national and regional sources indicated that physicians are generally paid between 49 percent and 63 percent of their collections while the Tuomey physician employees were paid an average of 131 percent of their collections. Other indicators of a financial relationship that did not satisfy the bona fide employee test were the unusual nature of the part-time, outpatient services only contracts; the 10-year contract term was highly unusual; the non-standard non-compete clauses; and the fact that the full-time benefits received by the physicians were inconsistent with Tuomey's normal policy of providing benefits to full-time employees only.

Tuomey Lessons Learned

Lessons to be learned from the *Tuomey* case include the following:

- Physician employment does not insulate physician contractual arrangements from Stark liability — The hospital argued that any amount paid by an employer to an employee who has a bona fide employment relationship with such employer for employment in the provision of covered items or services protected payments to employees even if such payments are in excess of fair market value for the service provided.
- Long-term arrangements are high risk and should be scrutinized carefully and reviewed periodically for compliance — The *Tuomey* employment contracts included 10-year terms, which is a very unusual term for an employment contract.
- Physician employment benefits should be consistent with other hospital employees — The *Tuomey* employment contracts included full-time benefits for part-time employment, which was not consistent with hospital policy.
- An independent fair market valuation opinion should be obtained from a well-qualified consultant who is familiar with the health care industry and is able to testify as an expert witness — Fair market value under the Stark law has some unique criteria that must be taken into consideration. Appraisers must be independent and knowledgeable about the health care industry in order to be considered experts.[65]
- Fair market value opinions should include supporting documentation and an explanation of the methodology behind the valuation opinion — The hospital relied on a three-page valuation opinion letter that described the transactions and concluded the compensation was consistent with fair market value but did not include supporting documentation or explanation of the valuation methodology utilized.[66]
- Fair market value opinions help; however, they are not guarantees, as experts may disagree on fair market value — The *Tuomey* fair market value report raised concerns because it indicated that 130 percent of net collections was fair market value even though it noted that the industry average paid similarly situated physicians 49 to 63 percent of net collections.
- The "commercial reasonableness" analysis must be thorough and complete and may be challenged if the payments to physicians are not comparable with other physicians in the community — *Tuomey* physicians were paid 130 percent of the physician's net collections, and the government argued that this fact, by itself, demonstrated that the compensation formula was not commercially reasonable.[67]
- It is important to document the purpose and intent of a contractual relationship with referral source physicians — It was the government's position that the hospital employed the physicians as a strategy to capture referrals and to prevent them from performing their procedures in-office or in an ambulatory surgery center.[68]
- Exclusivity, non-competition agreements, and part-time employment arrangements increase the risk level and level of scrutiny — In *Tuomey* the physicians did not have set hours for part-time employment, and the part-time employment contracts included the restrictions of non-competition and exclusivity of the physicians, which are not customary for part-time employment arrangements.
- Contractual arrangements that result in losses require a higher level of scrutiny to ensure they are defensible — The *Tuomey* court noted that the hospital had failed to document non-referral related reasons it was willing to incur a loss on the practices.
- The Advice of Counsel defense is not automatic — The *Tuomey* judge indicated

that the hospital could not rely on the Advice of Counsel defense if the hospital did not disclose full and accurate information, including all material facts, to its attorneys.

- "Opinion shopping" undermines the reliance on the Advice of Counsel defense — Tuomey had received multiple legal opinions of varying favorability and chose the best opinion as supporting documentation for the employment contracts, even though one counsel indicated that fair market value would not be accepted by government regulators, that the agreement was risky, and that the compensation was more than fair market value.[69]

Halifax Hospital Medical Center — Physician Compensation Included Bonus Based on DHS Not Personally Performed

In *Halifax Hospital Medical Center*,[70] a United States District Court in the Middle District of Florida granted summary judgment in favor of the United States in connection with its motion against Halifax Hospital Medical Center, finding that Halifax Hospital's submission of claims for DHS referred by six medical oncologists violated the Stark law. Halifax Hospital employed all of the staff, including the physicians who work at the hospital, through an affiliated staffing company.

Halifax Hospital paid all of the employee expenses, payroll obligations, and employee benefits of Halifax Staffing through a written agreement. The oncologist employment contracts with Halifax Staffing entitled them to receive a salary plus a bonus equal to 15 percent of Halifax Hospital's operating margin for its Medical Oncology program, which included fees for DHS that were not personally performed by the oncologists, such as fees for outpatient prescription drugs and other outpatient services. The bonus pool was to be divided between the six oncologists based on each individual oncologist's personally performed services.[71]

The district judge held that the bona fide employee exception to the AKS protected the arrangements with the physicians despite the physicians being employed by a separate legal entity, Halifax Staffing. Noting that Halifax Staffing was an instrumentality and alter ego of the hospital, the district judge applied the common law agency test and determined that the court had not been presented evidence that the physicians were controlled by Halifax Staffing rather than the hospital or that the physicians were independent contractors of the hospital. As a result, the compensation paid to the physicians was protected under the bona fide employee exception to the AKS, which does not contain a fair market value standard or prohibit compensation that is based on the volume or value of the physicians' referrals.[72]

Halifax Hospital argued that the transaction fit within the Stark law employee exception. The government argued, and the district court agreed, that the arrangement did not comply with the Stark law employee exception because that exception requires that services be personally performed by the physician, and here, the pool from which each bonus was drawn was "based on factors" in addition to personally performed services — including revenue from referrals made by the medical oncologists for DHS." Moreover, the court ruled that the Stark law employee exception does not permit hospitals to pay employed physicians in a manner that varies with, or takes into account, the volume or value of referrals.

The Court held that since the revenues of the Oncology Department, and therefore its profits, vary with the volume of patients that the oncologists treated at Halifax Hospital, the bonus component of the oncologists' compensation varied with the volume or value of referrals. Thus, since they did not meet a Stark law exception, the medical oncologists were prohibited from making referrals to Halifax Hospital for DHS, and Halifax Hospital was prohibited from submitting Medicare

claims for services furnished pursuant to such referrals.[73]

In addition, the district court held that Halifax Hospital's employment arrangement with two psychiatrists, from whom Halifax Hospital admitted that it had received DHS referrals, did not qualify for protection under the Stark law's employee exception. Although the court found that the psychiatrists' employment was for identifiable services and that the psychiatrists' compensation was commercially reasonable and constituted fair market value, the court held that the psychiatrists' incentive payments — equal to 100 percent of the hospital's gross collections less the amount of their salary and Halifax Hospital's cost for billing — took into account the volume or value of referrals.

The court reasoned that "[t]his arrangement would have allowed [the psychiatrists] to increase their incentive payments by making additional referrals for DHS to Halifax Hospital. Because the remuneration would vary with the amount of referrals, the Stark law employee exception would not apply to these compensation agreements." As a result, the district court refused to dismiss the Stark law claim related to the psychiatrists. The court held that there was insufficient evidence to establish the amount of the damages and that a genuine issue of material fact remains as to whether Halifax Hospital's conduct also violated the False Claims Act. The Court set a date in March 2014 for trial of these issues, as well as other Stark law claims and additional Medicare billing allegations that were not raised in the government's summary judgment motion.[74]

Halifax Hospital Lessons Learned

Lessons to be learned from the Halifax case include the following:

- Physician employment compensation may not vary based on the volume or value of referrals for designated health care services not personally performed — the Halifax bonus pool included fees for services that were not personally performed by the oncologists and therefore varied based on the volume or value of referrals for DHS not personally performed even though the pool was divided based upon each oncologist's personally performed services.
- Every attending or operating physician identified on a Medicare claim form is a referring physician with regard to DHS provided to such patient for whom reimbursement is claimed — Halifax claimed many of the referrals were made by other parties and that the fact that one of the oncologists was listed as the attending or other physician was not evidence that the physician made the referral for which the claim was submitted.
- Hospital indirect employment of physicians through an affiliated entity under an employee lease arrangement or similar mechanism will be analyzed the same as though the physicians were directly employed by the hospital — Halifax employed physicians through an affiliated staffing company that had contracting with the staffing company to provide medical staff for Halifax Hospital.
- It is important to obtain legal counsel review and approval of proposed hospital-physician transactions — Halifax had its counsel review the employment contracts, who concluded that the agreements violated the Stark law. Halifax then sent the agreements to outside counsel who stated that there was a reasonable argument that the employment contracts qualified for a Stark law exception.[75]

Intermountain Health Care — Physician Compensation Took Into Consideration the Volume or Value of the Physician's Referrals

Intermountain Health Care Inc., the largest hospital system in Utah and Idaho, agreed to pay the United States $25.5 million to settle claims that it violated the Stark law and the False Claims Act over a nine-year period by engaging in improper financial relationships with referring physicians.[76]

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The hospital-physician relationships at issue in this case included employment contracts under which Intermountain paid 37 physicians using a bonus formula that Intermountain admitted "may have improperly taken into account the volume and value" of the physicians' referrals to Intermountain; the hospital rented office space to 18 physicians "without written and executed leases in effect for the entire term and/or where there may have been fair market value issues with the leases;" and Intermountain had contractual agreements with 154 physicians that were not properly memorialized to avoid problems under the anti-fraud laws. Intermountain discovered the violations through its regular compliance review process and voluntarily reported them to the government.

Intermountain Health Care Lessons Learned

Lessons learned from the Intermountain Health Care case include the following:

- Voluntary disclosure will lead to reduced fines and penalties but can still result in significant fines and penalties — Intermountain voluntarily disclosed 37 noncompliance transactions, 18 noncompliance lease arrangements, and 154 financial arrangements without contracts (aggregate total of 209 illegal arrangements), yet they were only fined $25.5 million.
- The government may not require a corporate integrity agreement for voluntary disclosures — Intermountain was not required to execute a corporate integrity agreement.
- It is essential that hospitals monitor all physician transactions to ensure that written agreements are in place and have not expired — Intermountain did not have pre-payment audits, monitoring, or annual review of hospital-physician transactions as part of its compliance program.
- Hospitals should ensure that legal counsel or a compliance officer reviews all physician transactions to ensure that none of the compensation methodologies take into account the volume or value of referrals — Intermountain did not indicate that its in-house legal counsel and/or compliance officer had reviewed and/or approved the hospital-physician transactions.

Recent Enforcement Actions Related to Medical Office Leases

HCA-Parkridge Medical Center — Hospital Lease Payments to Physicians Determined to be in Excess of Fair Market Value

HCA, Inc., one of the largest hospital chains in the world, agreed to pay $16.5 million to settle allegations arising under the Stark law and False Claims Act. The settlement relates to a series of financial transactions between HCA subsidiaries Parkridge Medical Center and HCA Physician Services with a physician group, Diagnostic Associates of Chattanooga, through which it induced the physician members of Diagnostic to refer patients to HCA facilities by providing the physicians with illegal remuneration disguised as payments under real estate leasing arrangements and as an assignment of an existing real estate lease.[77]

In conjunction with the acquisition of Diagnostic, Parkridge leased space in a building owned by Diagnostic at rates which the government alleged were commercially unreasonable and excessive. The alleged misconduct also involved release of certain Diagnostic physicians from a separate lease obligation and solicitation and reliance on an erroneous real estate rent fair market value appraisal.

As part of the settlement, Parkridge entered into a comprehensive five-year corporate integrity agreement with the OIG to ensure its continued compliance with federal health care benefit program requirements. HCA also agreed to refund payments received for non-allowable costs claimed on prior Medicare cost reports

and to waive any rights to payment for any of the health care billings covered by the settlement agreement. The OIG expressly reserved the right to institute an administrative action seeking exclusion against HCA, Parkridge, and/or their officers, directors, and employees from Medicare, Medicaid, and all other federal health care programs.[78]

HCA Parkridge Medical Center Lessons Learned

Lessons to be learned from the HCA Parkridge Medical Center settlement include the following:

- Fair market value appraisals are required to support lease arrangements between physicians and hospitals — HCA Parkridge ignored the fair market value appraisal and entered into a lease arrangement that paid 50 percent more per square foot than recommended by the fair market value appraisal.
- If one disagrees with the results of the FMV opinion, continue to work with the consultant who gave you the opinion and convince him that his opinion is wrong rather than ignoring the opinion and then going to a new consultant, with the risk of turning the first consultant into a *qui tam* relator — the HCA Parkridge valuation appraiser became a *qui tam* relator after realizing that his or her recommendations were being ignored.

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Memorial Health Care System — Physician Lease Payments to Hospital below Fair Market Value

Memorial Health Care System, a nonprofit health system that operates Memorial Hospital in Chattanooga, Tenn. and Memorial North Park Hospital in Hixson, Tenn., recently agreed to pay $1.28 million to settle allegations arising under the Stark law, AKS, and False Claims Act.[79] The U.S. Attorney's office alleged that Memorial violated the Stark law over a six-year period by entering into medical office lease transactions with seven physicians and two physician groups that were below fair market value and that were "intended in part to induce the physicians … to refer patients to Memorial." In addition to the hospital space, physicians received free clerical and technical support and supplies. The medical office leases were time-share arrangements in which the hospitals rented the same space to different physicians or groups, each for a relatively short period of time.

In addition to the $1.28 million dollar settlement payment, Memorial agreed to refund payments received for unallowable costs claimed on prior Medicare cost reports and to waive any rights to payment for any of the health care billings covered by the settlement agreement. The OIG expressly reserved the right to institute an administrative action seeking exclusion against Memorial Health Systems and/or its officers, directors, and employees from Medicare, Medicaid, and all other federal health care programs.

Memorial Health Care System Lessons Learned

Lessons learned from the Memorial Health Care System settlement include the following:

- Fair market value appraisals are required to support lease arrangements between physicians and hospitals.
- Arrangements under which hospitals provide physicians with items or services for free or less than fair market value (*e.g.*, clerical and technical support and supplies) pose significant risk.

St. James Healthcare — Sisters of Charity of Leavenworth Health System — Physician Lease Payments to Hospital below Fair Market Value

St. James Healthcare, a hospital located in Montana, and its parent company, Sisters of Charity of Leavenworth Health System, a health care organization based in Colorado, recently agreed to pay $3.85 million to resolve allegations that they violated the AKS, the Stark law, and the False Claims

Act by improperly providing financial benefits to physicians and physician groups that made referrals to St. James.[80] The settlement resolved allegations that St. James and Sisters of Charity provided various improper financial benefits to referring physicians and physician groups by making payments to a joint venture that resulted in charging below fair market value lease rates to physicians renting space in a medical office building. St. James also allegedly provided incentives resulting in below fair market value lease rates for land on which the medical office building was constructed and other below fair market arrangements related to shared facilities use and maintenance. The settlement was the result of a self-disclosure by St. James.

St. James Health Care — Sisters of Charity of Leavenworth Health System Lessons Learned

Lessons learned from the St. James Health Care — Sisters of Charity of Leavenworth Health System settlement include the following:

- Fair market value appraisals are required to support lease arrangements between physicians and hospitals.
- Arrangements under which hospitals provide physicians with items or services for free or less than fair market value (*e.g.*, clerical and technical support and supplies) pose significant risk.

Recent Enforcement Actions Related to Personal Services and Management Agreements/Medical Director Agreements

Adventist Health System — Sham Medical Director/Teaching Services Contracts and Hospital Sales of Supplies and Inventory for less than Fair Market Value

Adventist Health System/West, dba Adventist Health, and its affiliated hospital White Memorial Medical Center agreed to pay the United States and the State of California $14.1 million to settle claims that they violated the False Claims Act.[81] The settlement resolved allegations that (a) White Memorial paid referring physicians compensation that the federal government contended was above fair market value to provide teaching services at its family practice residency program, and (b) White Memorial transferred assets, including medical and non-medical supplies and inventory, to referring physicians at less than fair market value. In addition, White Memorial allegedly owned medical practice groups through a sham foundation and provided recruitment loans and lines of credit to referring physicians that were not required to be paid back.

The White Memorial matter was a *qui tam* case initiated by physicians who further alleged that the hospital forgave loans to physicians and paid for travel and other costs physicians incurred to recruit other physicians to their medical practices. The allegations centered primarily on White Memorial and its relationship with two Southern California physician groups, Family Care Specialists and White Memorial Medical Group.[82] The federal government alleged that these improper payments violated the AKS and Stark law and, by extension, the False Claims Act.

As part of the settlement, White Memorial entered into a comprehensive five-year corporate integrity agreement with the OIG to ensure continued compliance with federal health care benefit program requirements. Although this case involved physician compensation agreements defined as teaching assistant agreements, the analogies to employment agreements and medical director agreements are apparent.

Adventist Health Care System Lessons Learned

Lessons learned from the Adventist Health Care System settlement include the following:

- Arrangements under which hospitals (i) provide physicians with items or services

for free or less than fair market value, (ii) relieve physicians of financial obligations they would otherwise incur, or (iii) inflate compensation paid to physicians for items or services pose significant risk.
- Hourly compensation for medical director/personal services should be based on fair market value salary surveys and include documentation to justify amounts paid.
- Hospital-physician contractual arrangements for loans, physician recruitment, and similar arrangements should be monitored regularly to ensure compliance with the terms thereof.

Cooper Health System — Sham Consulting Services Contracts

Cooper Health System has agreed to pay $12.6 million to settle allegations that it violated the federal False Claims Act and New Jersey False Claims Act by making improper payments to physicians under "consulting" and "compensation" agreements.[83] The United States and New Jersey alleged that from October 1, 2004, through December 31, 2010, Cooper recruited local outside physicians to serve on the Cooper Heart Institute Advisory Board (CHIAB). Physicians were paid approximately $18,000 a year to attend four meetings over the course of any given year. The United States and New Jersey alleged that at least one purpose of these payments was to induce the referral of patients to Cooper, that the payments did, in fact, induce such referrals to Cooper, and that Cooper's subsequent billing of the Medicare and Medicaid programs for services resulting from those tainted referrals were in violation of federal and state anti-kickback and self-referral laws and thus false claims.

In the civil settlement agreement, Cooper, in resolution of federal and state civil claims, agreed to pay $10,269,000 to the United States and $2,331,000 to the State of New Jersey. Cooper further enacted and agreed to maintain a number of corporate reforms designed to enhance accountability, training, and other aspects of its compliance operations. The Cooper settlement resolved a False Claims Act suit by a physician who was recruited to take part in the CHIAB but instead, recognizing its potentially unlawful purpose, demurred and filed a whistleblower — "*qui tam*" — action. Cooper was not required to enter into a corporate integrity agreement as part of the settlement. Although this case involved physician consulting and compensation agreements, the analogies to employment agreements and medical director agreements are apparent.

Cooper Health System Lessons Learned

Lessons learned from the Cooper Health System settlement include the following:
- Arrangements under which hospitals (i) provide physicians with items or services for free or less than fair market value, (ii) relieve physicians of financial obligations they would otherwise incur, or (iii) inflate compensation paid to physicians for items or services pose significant risk.

Methods for Effectively Auditing, Managing, and Investigating Hospital-Physician Transactions

Each of the above-referenced enforcement actions indicate increased risk association with physician employment, office space rental, and medical director agreement hospital-physician transactions and demonstrate the importance of having employment contracts, independent contractor agreements, medical office leases, equipment leases, mergers and acquisitions, loans, call coverage stipends, purchases, and other hospital-physician business arrangements reviewed by health care law counsel. The development and implementation of an effective compliance program that addresses hospital-physician transaction compliance risks is the best way to address the recent fraud and abuse enforcement actions.

Managing Hospital-Physician Transactions

The compliance officer should ensure that appropriate controls are in place to govern the physician contracting process. The compliance officer should not be directly involved in negotiating contracts with physicians, as the hospital needs to ensure independence of pre-payment review, ongoing monitoring, and post-payment review during the contract term.

Use of a Standard Form Transaction/Contract Checklist

A hospital should formalize the physician transaction process through the development, implementation, and maintenance of standard form contracts and transaction checklists that can be utilized in virtually all physician compensation relationships. The checklist should be prepared for every type of contractual arrangement and completed consistently for every contract. This checklist will provide a standard step-by-step process for creating, analyzing, and implementing a compliant financial relationship. For example, a medical director agreement checklist would include the following steps:

(1) identify the need for the services;
(2) project the number of hours required;
(3) demonstrate that the proposed medical director has the professional qualifications to perform the services;
(4) calculate fair market value compensation;
(5) describe the duties and requirements for the medical director;
(6) obtain legal review and approval;
(7) have the medical director execute the agreement; and
(8) document the medical director's completion of duties prior to payment.

Each arrangement should be subject to the same type of review, analysis, and documentation. If investigated, a hospital should benefit by demonstrating that it systematically analyzed each relationship in a meaningful manner. Any variations from this checklist or standard form agreement should be documented and explained.

Documentation that Written Agreements Are in Place and Contract Language Review Has Been Performed

A database of all agreements should be maintained and should include a reliable tracking system to ensure that each agreement is reviewed periodically. Documentation should contain certain information for evaluating compliance including: 1) identification of the need for the services; 2) projection of the number of hours required; 3) demonstration of the professional qualifications of the physician; 4) a copy of the contract/arrangement (or its term, effective date, expiration date, and automatic renewal provisions); 5) a description of the methodology used for the determination of fair market value of the compensation; 6) the amount of compensation, the method of payment, and whether the amount is based on the value or volume of referrals; 7) whether the arrangement satisfies the requirements of an anti-kickback safe harbor, Stark exception, and/or the procedures for a rebuttable presumption of reasonableness; and 8) confirmation of legal/compliance review and approval.

Document that Fair Market Value Analysis Policies and Procedures Have Been Followed

For each hospital-physician financial relationship, including all employment relationships and medical directorships, there should be a specific valuation memorandum on file which supports the fair market value nature of the transaction and articulates the manner in which the compensation was determined, the surveys utilized for comparison and benchmarking, and whether an outside valuation opinion was sought. Supporting documentation should include the manner in which the compensation was determined and if surveys

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were utilized and whether an opinion from a third-party valuation firm was sought.

For transactions above a certain amount, it is highly recommended to obtain a written analysis from an independent third-party consultant to support the fair market value of the payments. Valuation consultants should be retained through legal counsel to preserve, to the extent possible, attorney-client privilege. Legal counsel should be actively engaged in the valuation process to review draft valuation reports, provide comments to ensure compliance with applicable standards, and sign off on the fair market valuation review.

For significant transactions, the hospital board of directors should approve the transaction, after specifically reviewing and confirming both the fair market value nature of the purchase price and compensation to be paid to the physicians under the proposed compensation plan, as well as the "commercial reasonableness" of the transaction. It is essential that the valuator exclude from fair market value consideration any amounts that reflect a past or future referral stream or business otherwise generated between the parties.

Document that Commercial Reasonableness Analysis Policies and Procedures Have Been Followed

The hospital-physician contractual arrangement should be reviewed by the general counsel or a qualified third party to confirm that the proposed contractual arrangement is a sensible, prudent business arrangement that involves a legitimate business purpose for the parties. The arrangement should be essential to the functioning of the health care provider for there to be a sound business reason for paying compensation to a referring physician. A regular assessment of the arrangement should be conducted to determine if it is still needed. Document any non-referral related reasons (*e.g.*, community need for a physician specialty) that it is commercially reasonable to incur a loss on a practice or program.

Document that the Contracted Services Have Been Performed

Physicians should be required to complete a daily written activity log, time sheet specifying each task performed, and the amount of time spent performing the task. Proposed payments should be compared to contract terms for consistency, and expense reimbursements must be supported by invoices, check requests, and receipts.

Hospital-Physician Transaction Compliance Program Policies and Procedures and Training Related Thereto

Hospitals and physician organizations should develop written educational guidelines that address hospital-physician transactions and train relevant personnel to recognize those transactions that would result in a prohibition of patient referrals for DHS. Providers also should develop policies and procedures to timely refund identified overpayments or utilize the voluntary disclosure protocol.

Employee/Consultant Misconduct Reporting Requirement and Duty to Cooperate with Investigations

To reduce the likelihood that employees/consultants will become whistleblowers, all employment contracts or consulting agreements, and all employee separation or severance agreements, should include provisions that require the employee/consultant to report compliance misconduct, cooperate with compliance program investigations, and waive any right to recover money related to *qui tam* claims under the False Claims Act.

Retention of Health Care Law Regulatory Legal Counsel

Retention of competent health care law regulatory counsel is an essential requirement for hospitals and physicians engaged in compensation arrangements or transactions. Health law counsel should be able to assist with the development of fair

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market value/commercial reasonableness policies and procedures, review hospital-physician transactions presented for valuation review, prepare the valuation expert's retainer letter, and review the valuation expert's report. Legal counsel also may assist the client in gauging potential liability, evaluating whether to make a self-disclosure, and developing successful defenses and strategies for responding to government investigations.

Monitoring Hospital-Physician Contracting Arrangements

The compliance officer should ensure that appropriate controls are in place to govern the physician contracting process. All hospital-physician transactions should be analyzed by legal counsel and monitored for AKS and Stark law compliance. The compliance officer should not be directly involved in negotiating contracts with physicians, as the hospital needs to ensure independence of pre-payment review, ongoing monitoring, and post-payment review during the contract term. Key personnel, including employed or contracted physicians, should receive compliance training and updates on an annual basis regarding hospital-physician contracting policies and procedures.

Periodic Monitoring

Monitoring is a process involving ongoing "checking" and "measuring" to ensure quality control and involves daily, weekly, monthly, or other periodic checks to verify that essential functions are being adequately performed. Hospitals should periodically monitor (*e.g.*, every three months) all financial arrangements with physicians. Periodic monitoring will help providers identify any potential Stark law violations early so that repayment obligations will not be compounded over time. Reviews should focus on (i) payments without written contracts, (ii) unsigned agreements, and (iii) expired contracts where payments and services continue. Hospitals also should consider implementing tracking software that will send notifications if (i) a request for payment is made to a physician who does not have a current, fully executed agreement; (ii) a payment is received by a physician who does not have a current, fully executed agreement; and (iii) an agreement is approaching its expiration date and has not been renewed.

The hospital should task the Compliance Committee (or some other specially formed group or department) with developing a schedule pursuant to which each compensation relationship is periodically reviewed on an ongoing basis. In the physician-employment context, the review should focus on the services being provided and the submitted time and activity sheets. The review also should ensure that proper documentation and justification supports any changes to the relationship or compensation. With respect to other compensation relationships, the review should ensure that the parties are complying with the terms of the agreement and that the proper documentation supports the compensation and services.

Annual Review and Report to Board of Directors

Annual monitoring of all hospital-physician transactions should be undertaken to ensure that in each case the medical director is actually providing the services required and is being paid the compensation set forth in his or her agreement. Each review should be fully documented and may focus on the following:

- the true need for the services provided pursuant to the arrangement;
- ensuring the job descriptions are set forth in the agreement or otherwise properly documented;
- whether the full-time or part-time designation or expected time commitment is consistent with the services being provided under the arrangement and taking into account the physician's outside activities;

- whether the physician is actually performing all of the duties set forth in the agreement;
- whether the payments are being made as set forth under the agreement, and whether additional payments or other items of value are being provided to the physician;
- whether certain assumptions or factors have changed since the onset of the arrangement;
- reevaluation of the fair market value of the arrangement based on change in circumstances, if applicable; and
- amendment of the agreement if changes in the level of services, hours needed, or compensation are required.

Auditing Hospital-Physician Contracting Arrangements

Audits are formal reviews that include planning, identification of risk areas, assessing internal controls, sampling of data, testing of processes, validating information, and formally communicating recommendations and corrective action plans to the management team and board of directors. Compliance audits are necessary to demonstrate the effectiveness of a compliance program. An effective compliance program will detect potentially fraudulent activity that, if left undetected, could result in substantial civil and criminal fines and penalties. Auditing of hospital-physician contract arrangements should be a core compliance initiative subject to compliance audits.

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Conducting the Audit

Hospital-physician contract audits should follow the process outlined below:

- Step 1: Obtain the contracts and interview staff involved in obtaining physician signatures for contracts.
- Step 2: Confirm that a standard form contract was utilized and that legal counsel approved any deviations from the standard form.
- Step 3: Confirm that a contract checklist was completed.
- Step 4: Ensure that each contract is signed and current.
- Step 5: Identify the payment rate.
- Step 6: Identify the physician's duties.
- Step 7: Identify documentation requirements.
- Step 8: Determine whether listed duties are being performed.
- Step 9: Review transaction documentation for completeness and accuracy; verify timesheets, attestation forms, and other required documentation; and confirm that oversight was provided.
- Step 10: Verify that fair market value and commercial reasonableness is documented for each contract.
- Step 11: Review payments and compare payments to contracts.
- Step 12: Each payment should be matched to a contract and its required documentation.
- Step 13: Payments without a corresponding contract or documentation should be flagged for additional investigation.
- Step 14: Determine whether documentation and payments were consistent with contract terms.
- Step 15: Compare documentation to physician's schedule for other hospital or private office activities.
- Step 16: Review legality of compensation methodology.
- Step 17: Evaluate aggregate compensation.
- Step 18: Confirm that documentation of fair market value and commercial reasonableness are included in the hospital-physician contract file.
- Step 19: Determine continuing validity and necessity for the contract(s).
- Step 20: Identify contracts requiring updates.
- Step 21: Research payments without corresponding contracts or documentation.

The Audit Report

An audit report should be developed with an executive summary and sections for each type of hospital-physician transaction. The audit report should define the purpose and

scope of the audit and include a summary opinion/conclusion. The audit report should further include facts and findings, audit results, recommendations, documented areas of demonstrated compliance, and identification of existing compliance problems. The report should not make statements or reach conclusions regarding violations of law or regulations; however, noncompliant arrangements should be corrected immediately going forward. The final audit report should be issued to legal counsel, and legal counsel should be responsible for distributing the report to the compliance officer, management, and the board of directors.

When auditing or monitoring activities identify opportunities for improvement or compliance failures, it is often appropriate and/or necessary to take corrective action to address the findings. The audit report should include a corrective action plan, which describes the actions to be taken to address noncompliance areas, describes the mechanism for ongoing monitoring of the implementation of the corrective action plan, and describes the documentation and reporting processes associated with the corrective action plan.

Potential components of a corrective action plan include the following:

(i) adoption of a hospital-physician contracting policy;
(ii) revision of or supplemental compliance policies and procedures;
(iii) implementation and distribution of new compliance policies, procedures, and contract templates;
(iv) education of the workforce on new policies, procedures, and contract templates;
(v) monitoring to ensure compliance;
(vi) appropriate disciplinary action in the event of noncompliance;
(vii) restructuring or unwinding illegal financial arrangements; repayment; and
(viii) self-disclosure.

When corrective action is taken, follow-up auditing and/or monitoring should be conducted to confirm the effectiveness of the corrective action.

Conclusion

Hospitals entering into transactions with physicians must structure the relationships very carefully and exercise due diligence in documenting fair market value and commercial reasonableness. Compliance officers should be proactive and implement an effective compliance program which includes monitoring and auditing of hospital-physician transactions. It is important that compliance officers establish a process to evaluate all hospital-physician transactions from a legal compliance perspective, use third-party valuation expertise, and obtain board of directors' approval for certain types of transactions. Compliance officers and legal counsel should evaluate all hospital-physician transactions at the onset of the arrangement and should analyze fair market value and commercial reasonableness opinions to determine whether or not the backup documentation is adequate to defend the arrangement in the event of a government investigation or enforcement action.

If hospital-physician transaction compensation is unreasonable and above fair market value, there will be a high risk of government enforcement action. The $238 million *Tuomey* judgment and possible forthcoming $1 billion *Halifax* judgment are indicative of the significant financial penalties at risk when a hospital or health system enters into questionable transactions even when dealing with only a small number of physicians on the hospital or health system's medical staff. Each of the cases, and the other enforcement actions discussed, reiterate the importance of seeking the guidance of competent health care law counsel to ensure that any such arrangement is in compliance with all federal and state laws and regulations, including but not limited to anti-kickback and Stark.

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Endnotes:

1. Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013, Second Largest Annual Recovery in History, Whistleblower Lawsuits Soar to 752, Department of Justice Office of Public Affairs, December 20, 2013, www.justice.gov/opa/pr/2013/December/13-civ-1352.html.
2. 31 U.S.C. Section 3729-3733 (2009); See also, Guttler, Herschman, and Schaff, "Why and How to Conduct a Stark Audit in the Aftermath of Health Reform Legislation: A Practical Approach to Auditing Hospital-Physician Arrangements," American Health Lawyers Association In-House Counsel Program, June 27, 2010.
3. Cutler DM, Scott Morton F., "Hospitals, Market Share, and Consolidation," 310 *JAMA* 1964 (2013).
4. Hospital-physician transactions include practice acquisitions, physician employment and recruitment agreements, income guarantees, medical directorships, professional services agreements, risk-sharing agreements, practice acquisition agreements, on-call coverage arrangements, practice subsidy/stipend support agreements, clinical research agreements, electronic health records donations, service-line co-management, gain-sharing and pay-for-performance arrangements, medical foundations, office space and equipment leases, management services and billing agreements between physicians and hospitals, clinical joint ventures, accountable care organizations, hospital-based clinics, and hospital-affiliated group practices.
5. 42 U.S.C. §1320a-7b(b).
6. Social Security Act §1128B(b), 42 U.S.C. §1320 a-7(b)(b).
7. Social Security Act Section 1128(b)(7), 1128A(a)(7), 42 U.S.C. Sections 1320a-7(b)(7), 1320a-7(a)(7); See 42 C.F.R. Section 1001.951.
8. *See*, OIG Fact Sheet on the Federal Anti-Kickback Law and Regulatory Safe Harbors, oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.
9. 42 U.S.C. §1320a-7b(b)(3)(B). Defined covered items or services.
10. 42 C.F.R. §1001.952(i).
11. See generally, Susan O. Scheutzow and Steven A. Eisenberg, "The Employee Exceptions to the Anti-Kickback and Stark Laws After Tuomey: What's a Physician's Employer to Do?, J. Health & Life Sci. L., February 2011, at 151; and 59 *Fed. Reg.* 37202-08 (July 21, 1994).
12. 42 C.F.R. Section 1001.952(b).
13. *Id.*
14. CMS considers compensation "set in advance" if the aggregate compensation, a time-based or per-unit-of-service-based amount (whether per-use or per-service), or a specific formula for calculating the compensation is agreed to by the parties and set out in writing before any items or services subject to the agreement are furnished. The compensation formula satisfies the set-in-advance requirement if it 1) is set forth in such detail that it can be objectively verified and 2) is not changed or modified during the course of the agreement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.
15. 42 C.F.R. Section 1001.952(d).
16. DHS include the following services: clinical laboratory, physical therapy, occupational therapy, radiology, radiation therapy, durable medical equipment and supplies, parenteral and enteral nutrients, orthotic and prosthetic devices, home health, prescription drugs, hospital services, and speech language pathology. 42 U.S.C. Section 1395nn(a)(1)(h)(6).
17. 42 U.S.C. § 1395nn(a)(1)(A); § 411.353(a).
18. § 411.354(a)(1).
19. 42 U.S.C. § 1395nn(a)(1)(B); § 411.353(b).
20. 42 C.F.R. Section 411.353(d); See also Social Security Act §§1877(g)(2), 1877(g)(3), 42 U.S.C. §§1395nn(g)(2), 1395nn(g)(3), and 1395nn(g)(4).
21. *See, e.g.,* Katherine A. Lauer, Michael P. Myers, and Scott W. Morris, "*Amended False Claims Act Expands Liability for Inadvertent Stark Law Violations*," American Health Lawyers Association Institute on Medicare and Medicaid Payment Issues (March 24–26, 2010). www.healthlawyers.org/Events/Programs/Materials/Documents/MM10/lauer_amended_false_claims_act.pdf.
22. 42 U.S.C. Section 1395nn(e).
23. 42 C.F.R. § 411.357(d)).
24. 42 U.S.C. Section 1320a-7b(g); *United States ex rel. Wilkins v. United Health Group, et al.*, 659 F.3d 295 (3rd Cir. 2011)); *United States ex rel. Kosenske v. Carlisle HMA Inc., et al.*, 554 F.3d 88 (3d Cir. 2009).
25. 557 F. Supp. 2d 522 (M. D. Pa. 2008). Repko was ultimately dismissed for lack of subject matter jurisdiction.
26. *Id.* at 525.
27. 31 U.S.C. Sections 3729-3733.
28. *Id.* at 3729(a)(1).
29. *Id.* at 3730(b)(1).
30. *Id.* at 3733.
31. *United States ex rel. Wilkins v. United Health Group, et al.*, No. 10-2747, 2011 WL 2573380 (3d Cir. June 30, 2011); *United States ex rel. Kosenske v. Carlisle HMA Inc., et al.*, 554 F.3d 88 (3d Cir. 2009).
32. T. Mills Fleming, "New Government Scrutiny Demands New Strategies for Health Care Clients," 2011 WL 4454660, Aspatore (September, 2011).
33. Academic Medical Center, Employment, Certain Group Practice Arrangements With A Hospital, Equipment Lease, Fair Market Value Compensation, Indirect Compensation Arrangements, Isolated Transaction, Personal Services and Management Contracts, Physician Recruitment, Space Lease.
34. Ambulance Restocking, Equipment Lease, Personal Services and Management Contracts, and Space Lease.
35. 42 C.F.R. Section 411.351
36. *Id.*
37. 42 C.F.R. Section 411.351.
38. 42 C.F.R. Section 1001.952.
39. 69 *Fed. Reg.* 16128; See also 72 *Fed. Reg.* 51016 (Sep. 5, 2007), in which CMS indicated, "A fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided

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that the rate paid for clinical work is fair market value for clinical work performed and the rate paid for administrative work is fair market value for administrative work performed. We note that the fair market value for administrative services may differ from the fair market value for clinical services."
40. 72 *Fed. Reg.* 51015-51016.
41. (42 C.F.R. § 411.351; 69 F.R. 16087-88).
42. See 69 F.R. 16087.
43. For example ancillary services, "incident to" services, or the technical component of DHS charges.
44. (42 C.F.R. § 411.354(d)(2)-(3)).
45. See 69 F.R. 16066-068.
46. 42 C.F.R. § 411.357(c)(4)).
47. 69 F.R. 16087.
48. *Id.* at 16087-88.
49. *Id.*; See, also Pitfalls of Practitioner Compensation, Hawley Troxell in Health Law, December 20, 2011, www.hawleytroxell.com/2011/12/pitfalls-of-practitioner-compensation.
50. 752 F. Supp.2d 602 (W.D. Pa. 2010).
51. *Id.*
52. Space rental, 42 C.F.R. §1001.952(a); equipment rental, 42 C.F.R. §1001.952(b); and personal services and management contracts, 42 C.F. R. §1001.952(c).
53. "Surviving Fair Market Value & Commercial Reasonableness Thresholds," Health Capital Topics, Winter 2008.
54. This definition is based on guidance provided by the Centers for Medicare & Medicaid Services (CMS) in the preamble to the Stark II, Phase II regulations at 69 F.R. 16093 (March 26, 2004) and guidance provided in the "OIG Supplemental Compliance Program Guidance for Hospitals" at 70 F.R. 4866 (January 31, 2005).
55. See generally, Note 3 supra, at p. 146.
56. Gabriel L. Imperato, Fred Segal, "A Referring Nightmare: The Recent Government Scrutiny of Hospital-Physician Compensation Agreements — Lessons to be Learned from Recent Cases," 14 *Journal of Health Care Compliance* 5 (May-June 2012).
57. David B. Pursell, "Commercial Reasonableness: The New Target — Important Considerations for Negotiating and Drafting Hospital/Physician Agreements," 13 *Journal of Health Care Compliance* 59 (March/April 2011).
58. *United States of America ex. rel., Darryl L. Kaczmarczyk, et. al, v. SCCI Hospital Ventures, Inc.* d/b/a SCCI Hospital Houston Central, U.S. District Court, Southern District of Texas, Houston, Division, No. H-99-1031, July 14, 2004; See also, *United States ex. rel Roberts v. Aging Care Home Health, Inc., et. al.*, W.D. LA – Monroe Div., No. 02-2199, Feb. 16, 2007, wherein a home health agency was found to have violated the Stark law with respect to its medical director contracts. In ordering restitution of $400,000 to the Medicare program for amounts the agency had claimed on cost reports, the Court cited the agency's failure to comply with the personal services arrangements exception, particularly payments in excess of fair market value.
59. Martin D. Brown and W. Lyle Oelrich, Jr, "Commercial Reasonableness: Defining Practical Concepts and Determining Compliance in Healthcare Transactions for Physician Services," PYA Leadership Briefing (Business Valuation Resources, March 2013).
60. "Fair Market Valuation of Medical Director or Program Director Services," by Mayer Hoffman McCann and Kathy McNamara, filed with Plaintiff United States Designation of Expert Witness, July 12, 2005.
61. *Id.*
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63. *Id.*
64. *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, C.A. No: 3:05-cv-2858-MBS, 675 F.3d 394, 396 (4th Cir. 2012). Tuomey has already filed notice that it intends to appeal the court's judgment.
65. Albert "Chip" Hutzler, "Tuomey – Another Verdict – FMV Boxing Match Continues," American Bar Association Health Law Section Newsletter, September 2013, Volume 10, Number 1.
66. *Id.*
67. Mark R. Fitzgerald, "What Went Wrong at Tuomey Healthcare System," Powers Pyles Sutter & Verville PC, October 11, 2013 memorandum to Clients and Friends of the Firm.
68. *Id.*
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71. *Id.*
72. *U.S. ex rel Elin Baklid-Kunz v. Halifax Hospital Medical Center*, No. 6:09-cv-01002-GAP-TBS (M.D. Fla. January 8, 2014).
73. Note 63, supra.
74. Note 65, supra.
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