Medical Litigation Newsletter

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Venue À La Carte ?

"À la carte": to designate an option to choose at no extra charge; having unlimited choices with a separate price for each item. In *Kaiser v. Dr. A. Doll-Pollard and Southern Obstetrics and Gynecological Associates*, 398 Ill. App. 3d 652, 923 N.E.2d 927 (5th Dist. 2010), the Illinois Fifth District Appellate Court may have given patients' attorneys in certain medical malpractice cases the unlimited option to choose or to designate their choice of venue.

Kaiser was a medical malpractice action based on care and treatment that plaintiff patient received from defendant physician (the "Physician") in Clinton County, Illinois. The patient alleged that the Physician was negligent in performing a hysterectomy and providing post-operative care. The patient alleged that the Physician's operative notes indicated that she noted the existence of bleeding and attempted to locate its source, but ended the surgery and closed the patient despite the fact that the bleeding was not resolved. The surgery was performed in Clinton County. After the surgery and post-operative care were performed, a consulting cardiologist transferred the patient to a hospital in St. Clair County. The Physician did not treat or interact in any way with the patient's care and treatment in St. Clair County.

The doctors at the hospital in St. Clair County performed an exploratory surgery, during which they found and successfully treated the source of the bleeding. The patient alleged in her complaint that she suffered permanent injuries as a result of post-operative complications. The patient did not claim that the treatment she received at the hospital in St. Clair County was negligent, or that any of the treatment in that county was provided by the Physician or any agent of her employer. The patient alleged that venue was proper in St. Clair County because the diagnosis and treatment of the patient had occurred there, thus making it a county in which some part of the transaction that gave rise to the cause of action occurred.

The Physician moved to transfer the case to Clinton County on the basis of improper venue. She argued that the diagnosis and subsequent treatment of the patient's injury in St. Clair County did not justify venue in that county when the patient's entire cause of action sprang into existence in Clinton County. The patient argued that venue was proper in St. Clair County because some of her injuries resulted from the surgery she underwent there to diagnose and stop the bleeding. The circuit court denied the motion to transfer and the Physician appealed.

On appeal, the Physician argued that venue was appropriate in the county of residence of any defendant who is joined in good faith or in the county in which the transaction or some part thereof occurred out of which the cause of action arose. *See* 735 Ill. Comp. Stat. Ann. 5/2-101 (West 2007). As the Physician did not reside in St. Clair County, only the transactional prong of the venue statute was at issue.

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Hinshaw Representative Matters

Each issue of the *Medical Litigation Newsletter* will showcase a few cases that have recently been handled by Hinshaw lawyers.

We are pleased to report the following:

Patrick F. Koenen, a Partner in Hinshaw's Appleton, Wisconsin, office, received a defense verdict in a wrongful death case against a urologist in which plaintiff sought approximately $900,000 in damages. The patient was a 66-year-old woman who suffered from uterine cancer. She was taken into surgery by a gynecologist-oncologist to remove the primary cancer site and any areas of metastatic spread. The urologist was called in to do an intra-operative evaluation of a suspicious-looking adrenal gland. During that procedure, the gynecologist-oncologist biopsied a mass near the adrenal gland, with the urologist assisting. The mass was, in fact, the patient's pancreas. The pancreatic injury allowed leakage of acidic enzymes onto the patient's bowel, which caused it to perforate. The patient became septic and died 33 days later, after having undergone nine surgeries to try and save her. Plaintiff alleged that: the urologist had misidentified the mass and failed to note that it was a normal pancreas; the gynecologist-oncologist was relying on the urologist's expertise of organ location during the subject part of the operation; and the urologist gave the gynecologist-oncologist bad advice.

Michael P. Malone, *Brett B. Larsen* and *Jill M. Munson*, all attorneys in Hinshaw's Milwaukee office, recovered a complete defense verdict from a jury in a medical malpractice case in which approximately $2.5 million in damages were sought. Plaintiff, a 78-year-old patient, had lost her vision as a result of temporal arteritis, an inflammation of the arteries that supply blood to the optic nerves. The inflammation causes a buildup that eventually occludes the arteries and results in permanent vision loss. The patient claimed that defendant physicians failed to timely diagnose and treat her. Hinshaw represented the patient's primary care physician and one of his partners in their internal medicine group. Over the course of a two-week trial, Hinshaw's attorneys established that the patient's presentation was extremely atypical and that her symptoms were insufficient to alert the physicians that she had temporal arteritis. Additionally, a neuro-opthamologist testified that the patient's disease was so malignant that even earlier treatment would not have saved her vision.

In a medical malpractice action, the court looks to the allegations of negligence to determine where the cause of action arose. In determining whether venue is proper under a transactional analysis, the court must analyze the nature of the cause of action and the place where the cause of action arose. The cause of action arises where the agreed upon action is performed or where events occur that alter the parties' legal relationship. The Physician argued that the only transaction at issue in the case was the agreed upon medical treatment performed by her in Clinton County. In particular, the patient purportedly suffered injury in Clinton County allegedly as a result of the hysterectomy. This was the event that altered the parties' legal relationship.

The patient argued that venue was proper in St. Clair County because part of the transaction occurred in that county, in that it was there that her post-operative bleeding was diagnosed and she received treatment for post-operative complications. The patient did not allege that she received any negligent treatment in St. Clair County, or that the Physician provided any treatment in that county. However, she argued that at the time she left the Clinton County hospital, there was no diagnosis of internal hemorrhaging, and thus, no diagnosis of negligent surgery. The patient argued that those events were necessary in order for a tort of medical malpractice to exist.

The Physician maintained that the mere diagnosis and subsequent treatment by nonparties in St. Clair County of the complication from an allegedly negligent surgical procedure performed by the Physician in Clinton County was insufficient to confer venue in St. Clair County. She further contended that to sustain a medical malpractice action, the patient must show: (1) the standard of care in the medical community by which the physician's treatment was measured; (2) that the physician deviated from the standard of care; and (3) that a resulting injury was proximately caused by the deviation from the standard of care. It is not necessary to establish the extent of the injury or the extent of damages to hold a physician liable in a medical malpractice action. The Physician asserted that acceptance of the patient's argument would mean that the necessary elements of a medical malpractice case include the diagnosis of injury, something unsupported by Illinois law. The Physician also argued that in selecting St. Clair County, the patient made a "transparent choice motivated by brazen forum shopping."

Noting that the phrase "transaction or some part thereof" in the venue statute had been interpreted broadly, the appellate court analyzed two wrongful death cases relied upon by the patient: *Smith v. Silver Cross Hospital*, 312 Ill. App. 3d 210, 726 N.E.2d 697 (1st Dist. 2000), and *Bradbury v. St. Mary's Hospital of Kankakee,* 273 Ill. App. 3d 555, 652 N.E.2d 1228 (1st Dist. 1995). The courts in those cases held that venue was proper in the county where the cause of action occurred, which in a wrongful death action is the place of the decedent's death.

The Physician argued that as wrongful death actions, *Smith* and *Bradbury* were distinguishable. She reasoned that because death is the last element necessary to establish liability of an actor in a wrongful death action, a part of the transaction out of which the cause of action accrued is the place of death. The court found that although wrongful death was a separate and distinct cause of action, it was still premised on the underlying negligence. Accordingly, the court rejected the Physician's assertion that *Smith* and *Bradbury* were inherently distinguishable simply because they involved claims for wrongful death. However, it nevertheless found *Smith* and *Bradbury* distinguishable on other grounds.

The patient also cited *Tipton v. Estate of Cusick*, 273 Ill. App. 3d 226, 651 N.E.2d 635 (1st Dist. 1995), in support of her position. The patient in that case was prescribed and dispensed drugs in one county and ingested them in another. The drugs caused the patient to suffer a stroke. The court found that venue was proper in the town where the drugs were ingested. It

determined that the transaction or some part thereof clearly occurred in the county where the patient ingested the drugs and suffered a stroke because the patient did not have a cause of action until those events occurred. Similar to what was argued by defendant in *Tipton*, the Physician in *Kaiser* insisted that the patient had a cause of action before she was transferred and treated in St. Clair County. In fact, the patient had alleged that she had already suffered an actionable injury while in and before leaving Clinton County. Surprisingly, the *Kaiser* court reasoned that although the patient "could state a cause of action for medical malpractice based solely on the allegations of the injury in Clinton County, it is not the same cause of action . . . for the cumulative injuries . . . the patient sustained in both counties."

The *Kaiser* court's rationale is troubling because there seems to be an intermingling of the injury. More specifically, the court seems to confuse injury as it relates to one of the elements necessary to create a cause of action for medical malpractice with the injury that is simply alleged as a part of damages. The court cited *Peterson v. Monsanto Co.,* 157 Ill. App. 3d 508, 510 N.E.2d 458 (5th Dist. 1987), for the principle that when a patient alleges that injuries have occurred in multiples counties, venue is proper in any or all of them. In *Peterson,* 32 patients had sued physicians, an agricultural company and a chemical manufacturer, to recover for injuries incurred when the patients were exposed to herbicides manufactured and sold to a first utility and a second utility. The agricultural company moved to transfer from Madison County, Illinois, based on improper venue. The *Peterson* court noted that the agricultural company conducted no business in Madison County, but found that five of the patients had performed work there for the first utility and established that they sprayed and were exposed to herbicide there. Accordingly, the court held that part of the transaction did occur in Madison County in connection with those five patients. *Peterson* supports the Physician's position in *Kaiser* in that it demonstrates that under the transactional prong, venue is proper only in the county where the cause of action arose.

The Physician in *Kaiser* also applied the principles in *Jackson v. Ried*, 363 Ill. App. 3d 271, 842 N.E.2d 763 (4th Dist. 2006), to support her position. In *Jackson*, the patient alleged that defendant physicians were negligent in deciding to perform and execute a bilateral surgical implantation procedure. The patient filed suit in McClean County, Illinois, even though the treatment at issue was provided in Peoria County, Illinois, and neither of the physicians resided in McClean County. The patient alleged that part of the transaction out of which the cause of action arose occurred in McClean County because one of the physicians had ordered and reviewed radiographic studies that had been performed there. The *Jackson* court found that the patient's allegations of negligence concerned the decision to perform the procedure and the actual performance thereof. As a result, the court found the location of these acts to be critical in its analysis. Both actions had occurred in Peoria County. The *Jackson* court rejected the patient's argument that venue was proper in McClean County because the radiographic tests ordered by the physician had been performed there and were an integral part of her cause of action. The *Jackson* court noted that the patient had not alleged that there was anything negligent about the testing itself. The court further noted that it was the physician's interpretation of these studies and the physician's decision making based on it that were integral to the transaction, and both of those acts took place in Peoria County. As such, the court found that venue was proper only in Peoria County.

The *Kaiser* court noted the similarities between the case at hand and *Jackson* but stated that "standing alone, [they] are not dispositive." The court carved out a distinction in *Jackson* by stating that the court there did not hold that third parties' non-negligent acts can never establish venue pursuant to the transactional prong. The *Kaiser* court distinguished *Jackson* by stating that the type of injury incurred by the patient in *Kaiser* was "cumulative." The court explained that the complaint alleged that the patient had suffered permanent injuries as a result of the loss of oxygen to her brain and other organs because the patient began hemorrhaging when the hysterectomy was performed in Clinton County, and that it did not end until surgeons corrected it in St. Clair County. The court further explained that the complaint alleged that the patient suffered permanent harm as a result of an infection but did not know when or where the infection began, and that she suffered injury as a result of surgery to correct the bleeding in St. Clair County (however, the patient never alleged that her treatment performed in St. Clair County was negligent). The court found that the patient's alleged injuries occurred in both Clinton County and St. Clair County and held that the allegations of injury in the latter were an integral part of her action.

The court reasoned that "any injuries that occurred in St. Clair County as a result of intervening acts of third parties may also be attributable to the defendant's negligence as a normal incident to the risk she created." Curiously, it then cited in support three cases that are arguably clearly distinguishable from *Kaiser*.

The first case, *Easley v. Apollo Detective Agency, Inc.*, 69 Ill. App. 3d 920, 387 N.E.2d 1241 (1st Dist. 1979), was a criminal action in which the issue was whether to admit into evidence a threat made to the victim by the perpetrator (a security guard) after a criminal court proceeding which had arisen out of the perpetrator's assault on the victim to bring into question the perpetrator's character and to show that he was unfit for the job. The circumstances in *Easley* were clearly off the mark from those in *Kaiser*. The other cases, *Daly v. Carmean*, 210 Ill. App. 3d 19, 568 N.E.2d 955 (4th Dist. 1991), and *Simmons v. Lollar*, 304 F.2d 774 (10th Circ. 1962), were distinguishable because they were premised on damages, whereas the issue in *Kaiser* was where the patient's cause of action arose, which is where the last act occurred which triggered the cause of action.

One of the *Kaiser* court's most intriguing examinations involved the potential liability of a defendant in a medical malpractice case concerning his or her obligation to provide post-operative care to a patient. The court stated that the Physician had a duty to provide appropriate post-operative care until the patient was released from the hospital and that her alleged failure to do so consequently constituted ongoing negligence until the patient was released from the hospital. Citing *Wier v. Ketterer, M.D.,* 133 Ill. App. 3d 751, 479 N.E.2d 416 (5th Dist. 1985), the court decreed that the post-operative care that the patient received in St. Clair County "simply cannot be considered anything other than an integral part of the surgery the defendant performed in Clinton County."

As in *Kaiser*, the Fifth District erred in *Wier*. In *Wier,* plaintiff patient alleged that defendant doctor negligently failed to provide for proper medical supervision during the patient's transport in an ambulance that passed through St. Clair County traveling from Clinton County *en route* to St. Louis. The *Wier* court deduced that because the patient allegedly suffered injuries in St. Clair County during his transport through it, some part of the transaction occurred there, and so, venue was proper in that county.

Kaiser (as well as *Wier*) dangerously shifts the balance in favor of the patient with regard to establishing venue and encourages forum shopping. The holding eviscerates the transactional prong of the venue statute and is contrary to the public policy of striking a critical balance between the plaintiff's interest in choosing a forum and protecting the defendant from having to defend a lawsuit in a county with minimal or no relation to the defendant or transaction at issue. *Kaiser* could result in a chilling effect on physicians' decisions in choosing the appropriate hospital to transfer a patient for proper treatment which could affect the quality of medical care. For instance, a physician in Clinton County very well may decide (especially based on *Wier*) not to transport a patient through or to an undesirable forum. Who can guess *what* a court will say if the patient is air lifted?

The *Kaiser* court's reasoning that a physician has a duty to provide post-operative care until the patient is released, and, therefore, that the post-operative care the patient receives in another county is an integral part of the transaction that gives rise to the lawsuit, is clearly unworkable. If a surgeon negligently performs surgery on a patient in Cook County and the patient is later transferred to a hospital in St. Clair County due to a complication of the surgery, *Kaiser* stands for the proposition that the Cook County physician, who has no connection whatsoever to St. Clair County, can be sued in St. Clair County merely because he or she is responsible for the patient's post-operative care until the patient is released from the hospital. Furthermore, *Kaiser* arguably expands the elements necessary to prove negligence in a medical malpractice action by adding an additional prong—*the diagnosis and subsequent treatment of the injury*—that was not intended by the legislature and does not serve the public policy of the state of Illinois. As the Physician argued in *Kaiser*, nonparties' mere diagnosis and subsequent treatment of a complication from an allegedly negligent procedure performed by a defendant in another county should be insufficient to confer venue in the county where the nonparties' subsequent treatment occurred. *Kaiser* places minimal constraints on the patient's ability to designate the venue of the patient's liking as in the metaphoric concept of a venue à la carte.

By: Untress L. Quinn

Co-Management Re-Emerges as a Hospital-Physician Integration Option

Health care reform promotes performance-based pricing, value-based bundled payments, shared savings, and other payment models that are designed to focus on improving the value of care by improving quality and reducing costs. Clinical integration is a way for hospitals and physicians to bridge the gap between fee-for-service reimbursement and new value-based payment methodologies. The core feature of successful clinical integration requires the strategic alignment, collaboration and integration of hospital and physician goals. In order to recruit and retain physicians whose interest and efforts support service line growth, the hospital's goals for the service line must be aligned with those of the physicians. Engaging physicians in hospital service lines is critical to success, as physicians are the main driver of hospital volumes, profitability, quality and patient satisfaction. Hospitals that fail to achieve clinical integration with their medical staffs will be unable to effectively compete in a "value" driven health care economy.

One way physicians and hospitals are trying to achieve the goal of clinical integration is through co-management arrangements, which have re-emerged in recent years as a hospital-physician integration alternative to joint ventures or exclusive contract arrangements between hospitals and physicians who share mutual interests to lower costs, increase efficiency, and improve quality through evidence-based medicine, coordination of care, and outcomes measurement and reporting.

Defining Co-Management

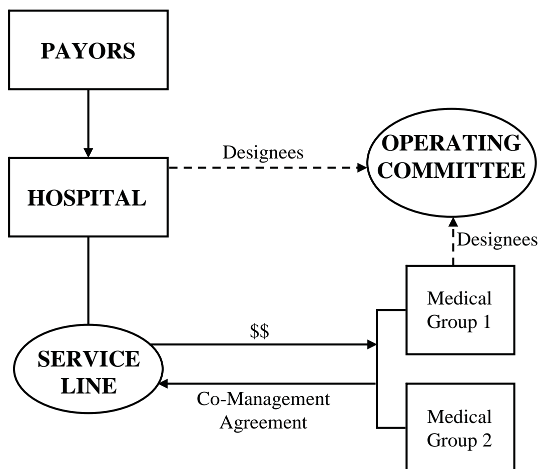
Co-management is a hospital/physician alignment strategy to elevate hospital service line performance. A co-management arrangement is an organized and formal mechanism to actively engage a group of physicians (may include one or more physicians, medical groups or faculty practice plans, or a joint venture entity owned in part or entirely by participating physicians and medical groups) to achieve greater

operational efficiencies and improved patient care outcomes. The goal and objective of the co-management arrangement is to recognize and appropriately reward participating medical groups for their efforts in developing, managing and improving quality and efficiency of a hospital service line. Co-management arrangements are typically focused on one clinical service line, such as cardiology, general surgery, orthopaedic surgery, oncology or spine surgery service lines. The co-management model may also be used with ambulatory surgery centers, outpatient imaging centers, emergency departments, radiation therapy, infusion centers, dialysis units, laboratories and mental health units. Cardiology is the most popular service line for clinical co-management; approximately 33% of large hospitals have introduced some form of cardiac clinical co-management arrangements.

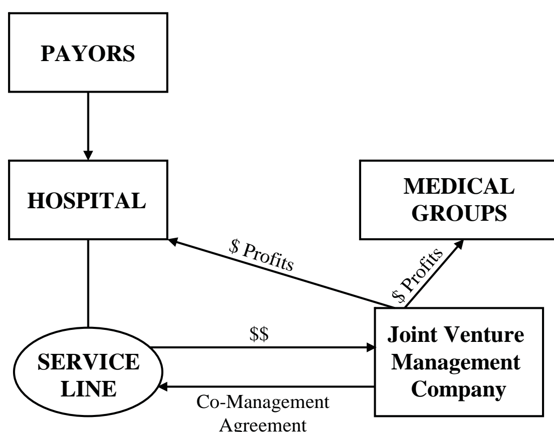
The Co-Management Model

Under the co-management model, a hospital will enter into a management agreement with an organization that is either jointly owned or wholly owned by a medical group to provide the daily management services for the inpatient and/or outpatient components of a hospital service line. Often, the hospital and the medical group develop an agreement between the health entity and a management company formed for the purpose of providing the service line management services. The management company is usually organized as a limited liability company (LLC), and the term of the co-management agreement is typically three to five years, renewable by mutual consent, with compensation adjusted annually. Ownership can be by individual physicians or by entities owned by individual physicians meeting investment criteria. Physician ownership is typically limited to physicians in a position to help the management company perform its services (e.g. practice in a relevant specialty). Hospitals or other health care organizations may also be an owner of the management company. Governance is generally delegated to a management board structured to provide representation of the participating specialties. Board subcommittees may be used to facilitate performance under the management agreement (e.g., finance committee, quality committee, and operations committee).

HOSPITAL SERVICE LINE CO-MANAGEMENT DIRECT CONTACT MODEL



HOSPITAL SERVICE LINE CO-MANAGEMENT JOINT VENTURE MODEL



How to Get Started

There are many issues associated with the strategic planning process to establish a co-management arrangement, including identifying duties and responsibilities for governance, management, and decision making, as well as establishing performance standards and reasonable compensation for services. The co-management model strategic planning process generally involves resolution of the following issues:

1. Governance and Organizational Structure. Form a steering committee that clarifies and reaches agreement on objectives, guiding principles, governance and organizational structure.

2 Co-Management Services and Responsibilities. Determine the scope of co-management services and responsibilities to identify the services that are included in the co-management arrangement, and to establish the responsibilities, duties, and authority of the co-managers.

3. Physician Participation Criteria. Develop a set of guidelines for initial and ongoing physician and medical group participation, including adherence to quality standards, confidentiality, and conflict of interest rules.

4. Performance Standards. Develop and implement key metrics on clinical, operational, quality, utilization management, patient satisfaction and physician performance. Set benchmarks and timeframes that serve to provide measurability and objectivity.

5. Co-Manager Compensation. Determine the methodology and quantity of compensation to be paid to co-managers, and ensure that such complies with legal and regulatory requirements.

To effectively coordinate the tasks inherent in the strategic planning process, an integrated work plan should be prepared. The strategic planning process should be the product of meaningful input from the hospital and physicians. There should be effective information systems in place to provide clinical data to the hospital and physicians in a useful format, to measure success in the pursuit of clinical guidelines and quality initiatives. Organizational budgeting processes should be utilized to promote the efficient and effective coordination of care across hospital service lines.

The Co-Management Agreement

A written contract between the hospital and physician group(s) is necessary to detail the scope and nature of the clinical co-management arrangement and to help demonstrate compliance with federal and state health care regulatory and fraud and abuse laws. The management services agreement development process will incorporate the governance and organizational structure, co-management services, roles, responsibilities and expectations of the parties; physician participation criteria; benchmarks, timeframes and performance measures; and co-manager compensation terms developed during the strategic planning process. Primary issues of negotiation are likely to include: the physicians compensation methodology; scope of services, quality improvement initiatives, use of research grant funds, medical office space for physicians, hiring and firing of non-physician clinical staff, billing and collections responsibility, termination, and restrictive covenants.

The co-management agreement typically requires the medical group to enhance the service line, create new service line opportunities, improve operations, integrate the physician members, and most importantly, align the goals of the physicians and the hospital around delivering high quality, efficient, and effective health care. The co-management agreement also generally requires direct physician participation in the design and oversight of annual clinical capital and operating budgets, the development and implementation of clinical protocols, performance standards and business plans, medical director services, patient case management services, materials management, physician and patient scheduling, nurse and non-physician clinical oversight, the periodic assessment of the quality of patient care delivered, the measurement of patient, physician and staff satisfaction, and the development of community relations and educational outreach programs.

Compensation Methodology

Co-management models provide fixed compensation as well as performance-based compensation. The fixed compensation is an annual fee (generally payable on a monthly basis) that is consistent with the fair market value of the time and efforts of the participating physicians in the service line development, management, and oversight process.

The incentive compensation, or bonus fee, is a series of predetermined payment amounts (which must also be at fair market value and is generally payable quarterly or annually) which are contingent upon the attainment of specified, mutually agreed upon, objectively measured targets. Potential incentive compensation measures include program development, clinical quality and outcomes, patient, physician satisfaction measures, and operational process improvements. Operational, quality and satisfaction-based performance measures are typically based on baseline levels determined using the facility's historical and clinical data and/or comparable national or regional data, with incentives paid to reflect incremental improvement. Performance measures should use an objective methodology, be verifiable, be supported by credible medical evidence, and be individually tracked.

Co-Management Program Legal Compliance Issues

Hospital-physician integration can not be achieved without legal risk. Contractual integration, such as co-management arrangements generates numerous legal issues and must be structured in a manner to comply with applicable antitrust, anti-kickback laws, physician self-referral prohibitions, and tax-exempt organization law.

Antitrust Laws. A Federal Trade Commission qualified clinically integrated arrangement is an arrangement to provide physician services in which (1) all physicians who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of physicians and create a high degree of interdependence and cooperation among the physicians, in order to control costs and ensure the quality of services provided through the arrangement; and (2) any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the joint arrangement.

Anti-Kickback Laws. The federal anti-kickback statute is a criminal statue that generally prohibits the offering, payment, solicitation, or receipt of any remuneration in order to induce referrals to another person or entity for the furnishing, or arranging for the furnishing, of any item or service that may be paid for in whole or in part by Medicare, Medicaid, or any other federally funded health care program. An improperly structured co-management arrangement could be interpreted as an agreement to provider remuneration to physicians in exchange for referrals. Co-management compensation structures must be both at fair market value and commercially reasonable, and must not be structured to reward physicians for increased volumes or for reducing care for Medicare and Medicaid patients, pursuant to Stark and anti-kickback regulations. Management fees paid to the co-management organization could be interpreted as remuneration intended to induce referrals to the hospital. To avoid anti-kickback law risk, the co-management arrangement must be structured in a way to comply with the personal services safe harbor/exception or other applicable safe harbor/exception for anti-kickback laws, economic terms must be consistent with fair market value, and the arrangement should include protections to prevent physician from selecting patients based on desirable acuities.

Civil Monetary Penalty Statute. The Civil Monetary Statute prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services to a Medicare beneficiary. A co-management arrangement that incentivizes behavior to reduce costs or otherwise change physician behavior could violate the civil monetary penalty statute. Co-management incentive payments should be structured to avoid civil money penalties for payments to physicians to reduce care. Length of stay and expense budget-based incentives may raise civil monetary penalty issues, however incentives can reward clinical improvement that correlates with reducing cost and reward cost-saving measures that do not adversely affect patient care. In OIG Advisory Opinion 08-16 the federal government approved a payment for performance arrangement between a hospital and physicians on the hospital's medical staff. Under the payment for performance program, a commercial insurer paid the hospital bonus compensation calculated as percentage of the annual base compensation it otherwise paid to the hospital if the hospital met specified quality and efficiency standards. The insurer would pay the hospital a maximum amount of bonus compensation of 4% of the annual base compensation. To receive bonus compensation, the hospital was required to meet quality standards for all hospital patients (including Medicare, Medicaid, and privately insured patients). The hospital entered into a quality enhancement professional services agreement with a physician entity for an initial term of three years, subject to automatic renewal for additional terms. Under the quality enhancement agreement, the hospital agreed to pay the physician entity a portion not to exceed 50% of the bonus compensation the hospital received from the commercial insurer for meeting the quality targets. Upon receipt of its payment, the physician entity will distribute the hospital payment to its physician members on a per capita basis. The program also includes a cap on payments to the physician entity, which is tied to the base compensation paid by the commercial insurer to the hospital. Any increase in patient referrals to the hospital due to an increase in annual base compensation received by the hospital from the commercial insurer would not increase the annual payment to the physician entity. In addition, the hospital was required to monitor the implementation of quality targets throughout the program to ensure that they do not result in inappropriate reductions or limitations on patient care—and the hospital agreed to terminate application of any quality target determined to have an adverse effect on patient care. Likewise, the hospital agreed to terminate physicians with significant referral increases to the hospital from participation in the program. The hospital will also inform all patients about the program in writing.

In its analysis of the hospital payments to the physician entity under the Civil Monetary Penalty law, the OIG declined to impose penalties due to the presence of the following program safeguards designed to reduce the risk of fraud and abuse:

- The quality targets are based on credible medical evidence indicating that they improve patient care;
- If a quality standard is contraindicated for a particular patient, the hospital payment to the physicians will not be reduced;
- The quality targets are reasonably related to the practices and patient population of the hospital; and
- The hospital will monitor the quality targets and their implementation throughout the program to avoid inappropriate limits on patient care or services.

The OIG also noted that the base compensation and bonus compensation paid by the commercial insurer to the hospital, as well as the physicians' quality efforts, involved all hospital patients admitted with the specified conditions—not just those patients insured by the commercial insurer.

Similarly, the OIG declined to impose administrative sanctions under the anti-kickback statute based on the presence of the following program safeguards:

- The membership of the physician entity will be limited to physicians who have been on the active medical staff for at least one year, thereby minimizing the likelihood that the arrangement will attract referring physicians or increase referrals from existing physicians;
- Compensation paid to the physician entity will be subject to a cap tied to the base compensation paid by the private insurer to the hospital in the base year so that increases in patient referrals to the hospital will not increase hospital payments to the physician entity;
- The physician entity's distribution of hospital payments to its physician members will be on a per capita basis—and participation in the program will be offered to all physicians, not just high-referring physicians (these factors will serve to reduce the risk of rewarding individual physicians for referrals to the hospital);
- The commercial insurer will oversee the arrangement to ensure that hospital payments to physicians are based on meeting the quality standards based on the *Quality Measures Manual* published by The Joint Commission with input from CMS; and
- The program will be limited to a three-year term (the OIG expressed no opinion on the potential future renewal terms of the program but nevertheless suggested that payments in subsequent terms should not be based on improvements achieved in prior years such that incentives for achievement of new improvements should be included in future terms).

Stark Law Self-Referral Prohibition. The Stark Law generally prohibits a physician from making referrals for certain designated health services to entities with which he or she has a financial relationship, unless an exception applies. Payments to physicians under a co-management agreement constitute a financial relationship. Designated health services include inpatient and outpatient hospital services; thus an exception to the Stark Law must be satisfied. The new Stark regula-

tions eliminated hospital-physician "under arrangement" transactions and proposed a new exception for certain "incentive payment and shared savings programs," such as co-management and gain-sharing arrangements. The proposed exception closely resembles the model of gainsharing programs approved by the Office of Inspector General (OIG) in a series of advisory opinions addressing Civil Monetary Penalty (CMP) and anti-kickback concerns. The primary difference between the proposed rule and the OIG-approved programs is that the proposed rule covers both pay for performance (as "incentive payment programs") and gainsharing arrangements (as "shared savings programs").

The proposed "Incentive Payment and Shared Savings Programs" exception ("Shared Savings Exception") provides that "[r]emuneration in the form of cash or cash equivalent payments, but not including nonmonetary remuneration, provided by a hospital to a physician on the hospital's medical staff or to a qualified physician organization" will not create a "financial relationship" for Stark Law purposes, provided that certain conditions are met. The CMS proposal to exclude such financial relationships from the operation of the Stark Law is relatively narrow, and CMS acknowledges that it is unlikely to cover many arrangements. Significantly, the proposed exception would protect only incentive payments and shared savings programs offered by hospitals. Further, CMS is proposing to protect remuneration only in the form of cash (or cash equivalent) payments made by a hospital, and the exception would be limited to payments to physicians who actually participate in the achievement of the patient care quality measures or cost saving measures. Under the proposed exception, the hospital may not determine eligibility for physician participation in a program based on the volume or value of referrals or other business generated between the parties. The proposed rule would also require written disclosure to patients whose patient care at the hospital relates to any of the measures that are part of the incentive or shared savings program.

Tax-Exempt Organization Requirements. Co-management arrangements raise two primary tax-exemption questions. First, if a new "umbrella" entity is formed (as opposed to using a series of agreements among existing entities), whether the entity can qualify for tax-exempt status; and second, whether any shared-savings or other payments between or among the hospital and physicians will be consistent with the tax-exempt status of the hospital. Tax-exemption rules require reasonable compensation; prohibit private inurement, private benefit or excess benefits; and prohibit co-management compensation from being based on "net earnings" or a hospital or service line. Co-management arrangements should obtain comparability data, independent approvals and documentation to establish rebuttable presumption of reasonable compensation under intermediate sanction regulations.

Conclusion

Integrated hospital-physician arrangements, which align clinical and financial interests, will be critical to the success of hospitals and health systems in the future value-driven health care delivery and payment system. Co-management agreements are a good option for hospitals and medical groups who desire to align physician incentives related to utilization, cost, service and quality objectives, but do not want to move to a more integrated model such as a medical foundation or employment model. Co-management agreements can enhance physician satisfaction by allowing them to participate in the operational and strategic efforts of the hospital. At the same time, the hospital can gain from possible cost reductions and secure key physician groups in one of the most important service lines of the hospital.

In order to avoid regulatory or compliance complications, an independent valuation consultant should be engaged to provide a certified opinion that the co-management arrangement is both fair market value and commercially reasonable, as well as to assist the health care enterprises involved in defining the scope of the activities performed by the co-management company and extensively review the appropriateness of the metrics that determine reimbursement. Experienced health care law counsel should be retained to structure the arrangement in a manner that complies with antitrust laws, the civil monetary penalty statute, anti-kickback statute, physician self-referral statute, false claims act, tax-exemption intermediate sanctions, and provider-based status rules.

Hospital boards of directors and executives should be taking steps to align their organizations with physicians as needed to sustain the level of physician integration required to achieve the goals and objectives of a value-driven health care delivery system. Clinical integration can address the challenges of health care reform, as long as hospitals develop the governance structure, physician incentives, quality and value metrics, and infrastructure to support a clinical integration program. Hospitals and health systems that develop successful hospital-physician alignment strategies will be able to sustain a competitive advantage by maintaining and enhancing revenue, utilization, and market share in both inpatient and outpatient care areas.

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