



Health Care Update

News on Joint Ventures

The Department of Health & Human Services Office of Inspector General (OIG) Issues Three Advisory Opinions Regarding Joint Venture Arrangements and Gainsharing Arrangements.

Advisory Opinion 08-10 (Aug. 26, 2008)

This opinion involved a joint venture between a cancer treatment facility and urology groups, where the urology groups would lease space, equipment and personnel to treat prostate cancer patients. The OIG found several features of the joint venture worrisome. The first concern, relates to the expansion by the urologists into a line of business where the success of the business could depend on referrals from the urologists. Second, the OIG noted that the same services were already provided by the facility (which billed Medicare) and the urology group referred patients to the facility for treatment, prior to formation of the joint venture. Third, the OIG was unable to exclude the possibility of prohibited kickbacks to urologists from the treatment facility. Thus, this type of venture could result in improper remuneration to the urology groups, which in turn, could result in federal penalties. A copy of the opinion is available by clicking here.

Advisory Opinion 08-09 (July 31, 2008)

This opinion concerned a medical center's arrangement to share a percentage of its cost savings with groups of orthopedic surgeons and neurosurgeons resulting from changes in operating room practices. The hospital identified 36 cost saving measures, including reducing

Seyfarth Shaw News

Deborah Gordon and **Joe Brown** co-authored "Healthcare Finance: A Primer" for the American Health Lawyers Association (AHLA). The book addresses the financing needs of various types of healthcare entities as well as the specific financial arrangements and the attending documents that are integral to them. In addition, the publication includes sample documents for various types of loans, and sample representations and warranties for life sciences companies and healthcare facilities.

William Schurgin is speaking at the AHLA 2008 Fundamentals of Health Law program.

Pam Devata addressed the applicability of the Red Flag Rules to healthcare entities to the Metropolitan Chicago Healthcare Council, AHLA's Professional Resources Department Resource Guide, Illinois Association of Health Attorneys and various other webinars.

Tom Shapira spoke at the mid-year meeting of the American College of Legal Medicine and addressed the various regulatory issues posed by the formation and operation of a retainer medical practice.

Deborah Gordon wrote an article, "Special Issues in Healthcare Transactions," for the summer 2008 edition of The Journal, a publication of the Association for Corporate Growth.

Kristin McGurn participated in the Women's Healthcare Executive program sponsored by the Massachusetts Hospital Association.

Deborah Gordon and **Joan Gale** gave a presentation to the Metropolitan Chicago Healthcare Council on "Corporate Compliance Issues in Healthcare."

Neal Goldstein presented at the quarterly meeting of the Milwaukee Orthopaedic Society on "Legal and Business Issues Related to Orthopaedic Group Mergers."

Mark Coffin, Neal Goldstein, and Tom Shapira have joined the Health Care Group.

surgical waste and product standardization for spine fusion surgeries. Although the OIG indicated that the arrangement could constitute an improper payment to induce the reduction or limitation of services and could potentially generate prohibited remuneration under the anti-kickback statute, the OIG concluded that it would not impose administrative or other sanctions. The OIG issued a favorable advisory opinion, noting that these types of gainsharing arrangements can be properly structured to serve legitimate business and medical purposes by increasing efficiency and decreasing waste. However, because gainsharing arrangements can influence physician judgment in a manner detrimental to patient care, they have to be carefully structured. A copy of the opinion is available by *clicking here*.

Advisory Opinion 08-08 (July 25, 2008)

This opinion addressed an investment in an ambulatory surgery center (ASC) by a group of orthopedic surgeons and a hospital. Under the arrangement, the physicians would own 70 percent of the ASC and the hospital would own the remaining 30 percent. The OIG issued a favorable advisory opinion, noting that the vehicle for profit would be the procedures actually performed by the physician-investors, rather than the referrals by these physicians, which made the arrangement less risky. In addition, the OIG concluded that the arrangement does not qualify for safe harbor for ASCs jointly owned by physicians and hospitals. A copy of the opinion is available by *clicking here*.

National News

Seventh Circuit Holds That Medical Residents May Qualify for Student Exception to FICA Taxes. On September 23, 2008, the United States Court of Appeals for the Seventh Circuit held that medical residents may qualify for the student exception from the payment of taxes under the Federal Insurance Contribution Act (FICA) and that the determination of whether a medical resident qualifies for the student exception is to be made on a case-by-case basis.

FICA taxes are imposed to support the social security system and are levied on wages paid by employers to employees. "Employment" is broadly defined, but it excludes services in the employ of a school, college, or university, or of certain organizations organized and operated, or to carry out the purposes of a school, college, or university, if the services are performed by a student who is enrolled in and regularly attends classes at such institution. This exception is generally referred to as the "student exception".

The University of Chicago Hospitals (UCH) sought a refund of FICA taxes it paid in 1995 and 1996 with respect to wages paid to medical residents on the basis that the residents qualified for the student exception. The IRS took no action on the refund claim and UCH subsequently filed a refund suit in District Court. The government argued that medical residents were not students and therefore ineligible for the student exception. The District Court rejected the government's motion and the government appealed to the Seventh Circuit of Court of Appeals.

The government argued on appeal that medical residents are ineligible for the student exception because (1) having already received a medical degree, medical residents are not students, and (2) a hospital is not a school, college or university in the common sense of the words. The court disagreed and found that a teaching hospital may indeed be considered as part of an affiliated university and that a medical resident may be regarded as a student even

though he or she has received a medical degree. The court further noted there is nothing in the statute that categorically excludes medical residents from eligibility for the student exception. The court therefore held that the student exception is not per se inapplicable to medical residents, but rather the applicability of the exception is to be determined on a case-by-case basis.

It is important to note that effective April 1, 2005, the IRS amended the Treasury Regulations applicable to the student exception in various ways that would appear to exclude medical residents from the student exception. For example, the amended regulations provide that an organization qualifies as a school, college or university if its primary function is formal instruction, it normally maintains a regular faculty and curriculum, and it normally has a regular enrolled body of students. The amended regulations further provide that an employee is a student if the services the employee performs are incident to and for the purposes of pursuing a course of study, and an employee whose normal work schedule is at least 40 hours per week is considered to be a full time employee and not a student because the services performed by the employee are not incident to and for the purpose of pursuing a course of study. The amended regulations also provide that if an employee is a licensed, "professional" employee (as defined in the regulations), that suggests that the service aspect of the employee's relationship with the employer is predominant.

However, in Mayo Foundation for Medical Education and Research v. United States, 503 F.Supp. 2d 1164 (D. Minn. 2007), the District Court of Minnesota ruled that the amended regulations are invalid because they are unreasonable and inconsistent with the plain meaning of the statute they are intended to interpret. The IRS has appealed the District Court's decision to the Eighth Circuit Court of Appeals.

In light of *University of Chicago Hospitals*, hospitals should consider filing claims for refunds of FICA taxes on wages paid to their medical residents, especially for FICA taxes paid before April 1, 2005. Although the amended regulations appear to preclude a refund for any FICA taxes paid after

April 1, 2005, as previously discussed, at least one court has found the amended regulations to be invalid. Therefore, although the law is not settled, hospitals should consider filing claims for refunds.

CMS Issues Rule Changes To Stark Physician Self-Referral Exceptions. In July 2008, the Centers for Medicare and Medicaid Services (CMS) published a display copy of its final 2009 Hospital Inpatient Prospective Payment System (IPPS) regulations. This is the third change in the past 18 months to the federal Stark law limiting physician self-referral regulations. One change includes the definition of a designated health services (DHS) entity. The revision changes the definition of DHS entity to include any entity that performs a DHS service, even if the entity does not bill Medicare for such services. In other words, under the new regulations, if one entity bills for services it has purchased from an entity that furnishes the service, both entities will be considered DHS entities. In addition, CMS clarified, without defining, "performed" to mean if the components of the services provided would allow the furnishing entity to submit a claim to Medicare, it has performed the service and would be considered a DHS entity. Accordingly, as a DHS entity, any referral by a physician owner of a joint venture would need to meet a Stark exception. CMS also prohibited percentage-based payments for space and equipment leases (although acceptable for payment for services) and unit of service (per-click) payments for space and equipment leases. The effective date of the majority of the provisions is January 1, 2009; however, the provisions addressing percentage-based payments and per-click payments will not take effect until October 1, 2009. In addition, as of October 1, 2009, traditional "under arrangements" joint ventures are no longer allowed. CMS explained that it prohibited physician ownership in joint ventures that provide services "under arrangement" with hospitals because it violates the rules prohibiting physicians from having an ownership interest in a service company. A copy of the rules is available on the CMS website.

On October 30, 2008, CMS put on public display the 2009 Physician Fee Schedule final rules. Included within those

rules are the final "Anti-Markup Rules." In general, the Angi-Markup Rules prohibit the markup of certain diagnostic tests that are purchased, or are deemed purchased, from an outside supplier. The Anti-Markup Rules will be published in the Federal Register on November 19, 2008, and are effective January 1, 2009. We will provide an analysis of the Anti-Markup Rules in a future *Health Care Update*.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) Was Enacted On July 15, 2008.

Under MIPPA, the mid-year 2008 Medicare Physician Fee Schedule (MPFS) rate of 10.6 percent has been replaced with a 0.5 percent update, retroactive to July 1, 2008. Because of Congress' inaction, this change has caused some delay in processing of claims and may require that some claims be reprocessed under the new level.

PhRMA Code Revisions Adopted. On July 10, 2008, the Pharmaceutical Research and Manufacturers Association of America (PhRMA), an organization that represents research-based pharmaceutical and biotechnology companies, adopted revisions to its 2002 PhRMA Code on Interactions with Healthcare Professionals. The revised code presents new guidelines on promotional items, meals and sponsorship of meetings. Among other things, the revised code prohibits distributing "reminder" items such as pens, pads of paper, tissues and hand soap as part of sales calls to healthcare providers; going to restaurants for meals; holding meetings at resorts; providing entertainment at meetings; and requires a clear delineation of the relationships of speakers and consultants. The revisions reflect a renewed effort by PhRMA to initiate self-reform. The revisions take effect on January 1, 2009, though it is likely they will be implemented sooner. A copy of the revised code is available on the PhRMA website.

Proposed 2009 Medicare Physician Fee Schedule Regulations Are Published. On June 30, 2008, the Centers for Medicare and Medicaid Services (CMS) released the proposed 2009 Medicare Physician Fee Schedule (MFS). A final rule should be issued November 1, 2008 and the

revised policies and payment rates become effective January 1, 2009. The proposed rules cover a wide range of topics affecting physician compensation and the manner in which physicians provide and are paid for services. Some highlights include: changes to the Independent Diagnostic Testing Facility (IDTF) enrollment requirements; clarification and proposed changes to the Purchased Diagnostic Testing or Anti-markup Rules; a new Stark exemption for incentive payment and shared saving programs (gainsharing); and proposed revisions to the Physician and Non-Physician Practitioner Enrollment Requirements. In comment letters to CMS (which were due by August 29th), physician groups and the American Medical Association (AMA) all overwhelmingly supported the gainsharing exemption; although, Congressman Stark, who authored the laws, believes the exemption is ill-advised. Physician groups strongly opposed the limits on billing for diagnostic tests performed in their offices.

Joint Commission Addresses Disruptive Behavior In The Workplace. The Joint Commission has issued an alert regarding intimidating and disruptive behavior in the workplace, proposing that it promotes medical errors, contributes to poor patient satisfaction and preventable adverse outcomes, increases the cost of care, and causes staff turnover. According to the Joint Commission, threatening and disruptive behavior diminishes communication and collaborative team effort, which are necessary for safe and quality patient care. To address this concern, the Joint Commission has issued a new Leadership standard (LD.03.01.01), effective January 1, 2009. The Joint Commission directs hospitals to adopt a code of conduct that defines disruptive and unacceptable behavior (EP 4) and to implement a process for managing inappropriate behaviors (EP 5). The Joint Commission suggests developing and implementing a reporting/surveillance system for detecting unprofessional behavior. While hospitals should work to lessen disruptive and intimidating behaviors in the workplace, hospitals must consider the labor implications of the Joint Commission's suggestions and proceed carefully. What some perceive as inappropriate

behavior, others, such as the National Labor Relations Board (the Board), might perceive as "protected concerted activity," especially if the harassment involves signing a union card. Hospitals should consult counsel before implementing a workplace policy against this type of conduct. In July 2008, the Board issued the non-healthcare case, *Standyne Auto. Corp.*, 325 N.L.R.B. No. 117 (July 31, 2008), in which it found that a company's statement during a campaign that harassment would not be tolerated was improper since it could be reasonably construed as restricting employees' § 7 activity.

Healthcare Institutions Need To Consider Whether They Must Comply With "Red Flag" Rules Designed To Prevent Identity Theft. As of November 1, 2008, certain Healthcare Institutions will have to comply with regulations established to protect the public against identity theft. These regulations, known as the "Red Flag" rules, were issued jointly by several federal agencies and are directed at banks, mortgage lenders and other traditional creditors; however, they define creditor so broadly that some Healthcare Institutions will need to comply with them. The regulations require affected companies to develop and implement written identity theft prevention programs to identify, detect, and mitigate against identity theft when certain "red flags" are present. The Fair and Accurate Credit Transactions Act defines a red flag as a pattern, practice, or specific activity that indicates the possible existence of identity theft. The regulations cover Financial Institutions, Creditors and users of Consumer Reports and require that they develop written policies and procedures to comply with the FCRA's Identity Theft Provisions. Depending upon whether you are a Financial Institution, Creditor or Consumer Report user, your responsibilities will differ, although all affected companies must adopt and implement broad identity theft prevention systems. The regulations also require that a health care organization's board of directors (or other governing body) become involved with the identity theft prevention programs. Failure to comply could result in sanctions.

Act Expanding Scope of ADA Becomes Law. President Bush recently signed the Americans with Disabilities Act

(ADA) Amendments Act (ADAAA), which expands the scope of the ADA. Under the ADAAA, which is effective January 1, 2009, millions of Americans may now be able to claim to be disabled even though they did not qualify under the old law. One change is that using "mitigating measures" such as medications, artificial limbs and hearing aids will no longer be considered when determining whether a person is disabled. Also, an impairment that is episodic or in remission could still be considered a disability if it would limit a major life activity when active. These changes were designed to protect people with epilepsy, diabetes or cancer, who were not protected under the old law. The Act is the culmination of several months of negotiation between the business community and disability advocates. Employers need to immediately look at their existing policies, handbooks, procedures and job descriptions to determine whether they may now be at risk for a lawsuit under the ADAAA. It is likely that the ADAAA will spark new lawsuits brought by plaintiffs seeking to test the law. The FTC recently announced it will suspend enforcement until May 1, 2009.

The Status of the Proposed Revisions to FMLA
Regulations Is Unclear. The Department of Labor (DOL)
issued proposed revisions to the FMLA regulations in
February 2008, and thousands of comments were submitted
in April. The regulations have not been amended since 1995.
The proposed revisions make a number of changes that
will assist employers in compliance with the FMLA. They
also included a number of revised and new FMLA forms.
The DOL has not issued any news lately on when (or if) the
final version will issue, but if DOL is going to revise these
regulations, it is expected that DOL will do so this month.

Attorneys General Call On HHS To Abandon "Right Of Conscience" Regulation. Attorneys General (AGs) from 13 states called on the Department of Health and Human Services (HHS) to abandon a proposed regulation that would prohibit discrimination or retaliation against healthcare workers who refuse to participate in any abortion-related services because of their religious or moral objections. In their formal letter, the AGs expressed their concern that the rule would jeopardize women's access to birth

control and impact the delivery of healthcare services. The proposed rule, which was announced in August, was intended to increase awareness of the "right of conscience" laws protecting health care providers. In a separate letter, a key hospital industry group asked HHS to withdraw the proposal and to embark on a more deliberative process to fully analyze the issues. HHS acknowledged that it received a number of comments (both pro and con) and that will consider them during the notice and comment process.

State News

Prominent Catholic Hospital Loses Property Tax Exempt Status. In a much-anticipated decision, the Illinois Appellate Court, Fourth District, sided with the Illinois Department of Revenue and local taxing authorities who had found that Provena Covenant Medical Center was not entitled to a property tax exemption as a religious and charitable institution. Applying a very deferential standard of review, the Appellate Court found no reason to upset the Department of Revenue's decision that the hospital's charity care did not justify an exemption. The trial court had reversed the Department's decision but the Appellate Court disagreed, finding that the decision should stand. At the time the tax exemption was removed, the hospital's charity care level was less than one percent of its revenue. At issue for the hospital is a property tax bill that could cost it as much as \$1 million per year. According to the court, simply being a nonprofit "in the hospital business" is not sufficient to establish charitable status under Illinois law. The court did not believe that the hospital demonstrated "general benelovence" as is required for a charitable and religious institution. In so ruling, the court rejected the hospital's "community benefit" claim. The court also rejected the hospital's argument that it should be exempt as a religious institution, since the building was used primarily for the secular purpose of providing health care services, and not as a place of religious worship or instruction. The hospital has announced that it will ask the Illinois Supreme Court to review the case. Provena Covenant

Med. Ctr. v. The Dep't of Rev., 2008 III. App. LEXIS 867 (III. App. Ct. 4th Dist. Aug. 26, 2008).

Illinois Law Does Not Allow Physicians To Split Fees Based On Percentage Of Professional Income. The Illinois Appellate Court held that a percentage-based fee arrangement between a physician group and a medical billing company was prohibited and void under the state's Medical Practice Act (MPA), 225 ILCS 60/22(A)(14) (2008). A group of sport medicine physicians contracted with the defendant company to provide billing, accounts receivable, and collection services at a rate of 4.5 percent of all reimbursements and 6.25 percent of all claims not originally processed by the defendant. The plaintiff sued, alleging the defendant breached the contract by failing to perform services. In response, the defendant argued that the contract was void under the MPA. The trial court agreed with the defendant and granted summary judgment. Affirming on appeal, the Appellate Court found that this type of percentagebased fee splitting arrangement, though common in physician arrangements with billing companies, is void in Illinois "irrespective of the purpose and common practices involved in medical billing agreements." The court was concerned that fee splitting arrangements could lead to fraud and abuse, because the physician might be motivated by financial selfinterest rather than the professional's competence. However, the Court expressly noted that other fee arrangements, such as a flat-fee based upon the volume and complexity of the services, would probably be valid and enforceable. The court applied a bright-line rule, finding that the MPA bans sharing, pooling, dividing, or apportioning professional fees, regardless of the reason or whether the parties' agreement implicates the anti-fraud and abuse policies behind the MPA. Ctr. for Athletic Med. Ltd. v. Independent Med. Billers of III. Inc., 889 N.E.2d 750 (III. App. Ct. 1st Dist. 2008). The decision is likely to be appealed to the Illinois Supreme Court. If affirmed by the Supreme Court, or not appealed, this decision would have significant implications on medical providers who will be forced to make material changes to their arrangements with billing companies.

Illinois Enacts Hospital Uninsured Patient Discount Act.

The Illinois legislature unanimously overrode Governor Blagojevich's amendatory veto to enact the Hospital Uninsured Patient Discount Act (the "Act"), which took effect September 23, 2008 (although a few parts of the bill do not take effect until December 22, 2008). The Act requires Illinois hospitals to provide substantial discounts to eligible patients. Eligible patients are uninsured Illinois residents with a family income of not more than 600% of the federal poverty level (FPL)(which is \$127,200 for a family of four in 2008) (300% at critical access and rural hospitals, which is \$63,600 for a family of four in 2008). The discounts limit the charges to 135% of the hospital's cost (as shown on its most recently filed Medicare cost report). The discount is applicable only to charges exceeding \$300 in any one inpatient admission or outpatient encounter. The Act also imposes a cap (25% of annual gross family income) on the amount a hospital can collect from an eligible patient in any 12-month period for medically necessary hospital services. However, hospitals may exclude from this cap eligible patients with assets (such as a primary residence and certain personal property) of more than 600% of the FPL (300% at critical access and rural hospitals). Every hospital bill to an eligible patient must include a prominent statement that the patient may qualify for the discount and information regarding how to apply for the discount. Patients may be required to apply for Medicare, Medicaid, AllKids, SCHIP, or other public programs, if there is reasonable to believe they are eligible. Patients must be able to provide third-party verification of their income. The Act applies to health care services provided no earlier than April 1, 2009. The Attorney General is responsible for promulgating any necessary rules and for administering and enforcing /the Act. Hospitals in violation of the Act are subject to injunctive relief, civil penalties up to \$500 per violation, and possible adverse licensure action.

Trends to Watch

The Concierge Model of Medicine. Physicians, frustrated with the economics of running a medical practice in the current climate, where reimbursement for medical services is declining and costs are escalating, are turning to "concierge" or "retainer" models for their practices. Under this model, physicians significantly reduce the size of their practice to only those patients who have paid an annual fee, which is typically between \$1,000 to \$3,000 per year. The annual fee does not cover the actual medical services provided, other than a comprehensive annual physical exam. Patients are still required to pay the applicable office fee for the physician's services. Ancillary services, which may be performed by other providers outside the physician's practice, are usually not included in the annual fee and patients are billed directly by the provider of such services. A smaller practice allows the physician to spend more time with the patients, provide same or next-day appointments and 24/7 access to the physician via pager or e-mail. Concierge physicians have found that this model permits them to be more proactive with their patients and promote wellness and preventative care, rather than short, rushed appointments to treat a discreet illness or injury. Commercial payors have generally not been receptive to the concept and argue that the arrangement constitutes an improper "access" fee. As a result, many concierge practices have terminated their contracts with third-party payors and function as out-of-network providers. Another potential issue relates to Medicare, which does not allow physicians to charge patients for services that are already reimbursed by the Medicare program. It is important to structure the benefits members receive in exchange for the annual fee to ensure that Medicare enrollees are not charged in a manner that violates the regulations. The American Medical Association (AMA) does not track the number of concierge practices there are in the United States, however, in 2004 the Government Accountability Office counted 146 such practices. In 2003, the AMA issued "Code of Medical Ethics Opinion 8.055 Retainer Practices," in which it discussed ethical concerns with this type of practice.

(See AMA Retainer Practices). A handful of companies have introduced concierge care into their executive health benefits.

AMA Announces Principles For Medical Tourism Industry.

Globalization has hit the health care industry in several respects – such as the outsourcing of medical record keeping, the reading of x-rays, the recruitment of foreign nurses and medical tourism. Medical tourism is a booming industry and is expected to grow to an estimated \$40 billion annually by 2010. Medical tourism, where patients go abroad for medical treatments – from elective cosmetic surgeries at vacation spots to chemical dependency programs to critical care that patients cannot otherwise afford. Major destinations for treatment are India, Malaysia, Singapore, Thailand, the Philippines, Argentina, Brazil, Costa Rica, Mexico and Panama. As a cost-saving measure, large employers offer employees the option of receiving medical care abroad. Recognizing the surge in this industry, the AMA

recently issued guidelines setting forth several principles for patient consideration before seeking medical care abroad. The first principle is that the treatment must be voluntary. Another principle is that arrangements must be made for follow-up care to be received at home, including covering the cost of that care. Other concerns the AMA identified are seeking treatment only from accredited facilities, transferring patient medical information (consistent with HIPAA privacy guidelines), informing patients of the risks of combining traveling and "vacationing" with some medical procedures. The AMA intends to introduce model legislation to insure that those who facilitate medical tourism follow these principles. The guidelines are available on the AMA website. In a related vein, employers with employees overseas are increasingly implementing a medical evacuation plan to assist employees who become ill or otherwise need to evacuate from overseas. Evacuation plan insurance is also available.



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