Orthopaedic Legal News

#### EMERGING ORTHOPAEDIC-LEGAL ISSUES

JANUARY, 2012-SPECIAL EDITION

**Cal Ortho On-Line** will provide COA members with timely and relevant information on emerging issues affecting orthopaedic practice.

Topics will range from new health delivery models, strategies to make your practice successful, the use of physician extenders, and updates on recent legal/regulatory developments.

This publication will only be made available to COA Members as of February, 2012.

Be sure that your membership is current so that you and your practice manager continue to receive this publication.

### **Upcoming CME/QME Events**

Effectively Working Within Your Workers' Compensation System

Tuesday, February 7, 2012

Moscone Convention Center-San Francisco
Held in conjunction with the
AAOS 2012 Annual Meeting.
Course is accredited for 6 OME CME Hours.

#### COA 2012 Annual Meeting/OME Course

April 19-22, 2012

Park Hyatt Aviara, Carlsbad, CA (North San Diego County) This meeting is accredited for 18.75 Category I CME hours and 6 QME CME hours

Registration is available online at www.coa.org

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In light of the debate in Sacramento concerning whether medical corporations can employ physical therapists, one of the most pressing issues for orthopaedic surgeons is whether their medical corporation will continue to be able to employ physical therapists. In this process, we are also looking at what services other ancillary staff can perform in an orthopaedic office.

The next edition will focus on this topic.

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JANUARY, 2012-SPECIAL EDITION

Editor: Astrid Meghrigian, JD

# Options for Physicians to Partner with Hospitals

**New Frontiers:** 

Strategic Planning for the Success of your Orthopaedic Practice

To be presented at COA's
2012 Annual Meeting/
QME Course
April 19 –22, 2012
Park Hyatt Aviara

Carlsbad, CA

(North San Diego County)

Go to: www.coa.org for the complete agenda and to register for the meeting.

## OPTIONS FOR PHYSICIANS TO PARTNER WITH HOSPITALS

For years, the concept of physician "alignment" or "integration" with hospitals has been a hot topic in health care, with scores of articles and consultants exulting the needs and benefits of such relationships. To be sure, there can be benefits to both sides when physicians and hospitals join forces. Just *some* of the potential advantages both parties historically could receive include:

#### **PHYSICIANS**

#### HOSPITALS

Increased reimbursement Increased referrals

Decreased overhead costs

Increased leverage with payers

Reduced administrative challenges Controlled costs

Access to increased capital, Improved quality equipment, and technologies

Security and income stability Increased patient satisfaction

Improved work-life balance Increased ability to recruit physicians

Health reform and recent market forces have only fueled efforts to more closely "align" physicians and hospitals. The Patient Protection and Affordable Care Act (PPACA) includes payment reform initiatives that reward value of care over volume, such as shared savings programs, bundled payments, and penalties for preventable readmissions and hospital-acquired conditions. Commercial payers have already adopted or plan to embrace these methodologies. However, the success of these efforts necessarily depends on collaborative relationships between physicians and hospitals, making the acoustics for "alignment" even louder. As a result, many orthopaedic surgeons understandably want to know what models exist in California and whether those models are viable options.

To be sure, there are a number of options that are being explored by physicians and hospitals that provide varying degrees of integration. They range from medical staff membership to hospital employment (where lawful).

Regardless of the option chosen or contemplated, there are a number of issues physicians should consider first

#### Share the same values and goals.

First and foremost, based in part on the history of physician-hospital relationships, it is now uniformly accepted that no model will work without involved and empowered physicians who meaningfully participate in key decisions impacting quality. Consequently, "alignment" should not be considered a mere contracting strategy with third party payers, but as a "partnership" whereby physicians have a voice that is heard and recognized in a truly collaborative relationship that is committed to quality patient care.

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## CalPERS New Coverage Policy

Prior to partnering with anything or anyone, it is important orthopaedic surgeons understand the market conditions in their communities, so that they can meaningfully assess their options. As part of that analysis, an understanding of the payer mix (HMO, PPO, Medicare etc.) and what those payors are doing is critical. This is particularly true where the payor is self-funded and; therefore, able to fashion a more limited benefit design to reduce employer costs.

CalPERS HMO plan, administered by Blue Shield of California is a case in point. Effective January 1, 2012, Blue Shield CalPERS HMO members who need non-emergent knee or hip replacement surgery are required to have that procedure done at one of Blue Shield's "Preferred Centers for Knee and Hip Replacement Surgery." Currently, Blue Shield has only designated 20 such preferred facilities for all of California. In ordered to be designated a "preferred facility" the hospital/surgeons must meet quality standards and the facility must agree to a negotiated reimbursement rate.

Blue Shield's informational materials state that neither the physicians who performs non-emergent procedures at non-preferred facilities or the non-preferred facility will receive any reimbursement for their services.

CalPERS intends to expand this policy to other services such as spine surgeries, cancer and cardiac care, etc.

COA is meeting with CalPERS and Blue Shield to discuss this program. We are also meeting with the Department of Managed Health Care to express our concerns with the limited access for patients.

#### Consider the facts.

There may be situational factors that must be analyzed when deciding whether, and if so how, physicians should partner with hospitals. An orthopaedic surgeon who is close to retirement or is committed to practicing with complete control may not be the ideal candidate for a partnership. In addition, some options require the involvement of a group of physicians and; therefore, would be harder to be available to a physician in small or solo practice. How many hospitals there are in a given community, their respective size and financial condition, and the number and extent of relationships these facilities have already with physicians may also impact which models are realistic. Further, even benefit designs and other actions by third party payers should be considered. For example, if the predominant payer in the community is selective contracting with only a few hospitals for orthopaedic procedures, an exclusive contract with an excluded hospital probably would not make sense.

#### Analyze the law and weigh the risks.

Each model raises legal issues that affect its implementation and operation. The laws impacting physician-hospital partnerships, while complicated, provide ample armor for both state and federal anti-fraud enforcers and whistleblowers (often competitors) under the False Claims Act to bring lawsuits alleging fraud violations. These legal actions can and do result in prison time and hefty fines. Consequently, it is essential that orthopaedic surgeons discuss these options with their legal counsel to discuss the risks and benefits and determine the best strategy that meets their needs.

With these considerations in mind, potential "partnership" options that are relevant to orthopaedic surgeons are generally summarized below. Many of these options are not mutually exclusive and it is essential that orthopaedic surgeons understand their options in light of the rapidly changing marketplace. As Jeremy Miller, Esq., a California health care attorney recently concluded:

"Some physicians view the prospect of greater alignment with hospitals as an opportunity to have a significant role in the creation of a value-based, coordinated, patient-centric health care delivery system. Other physicians, with some justification, fear they do not have the resources to prevent themselves from becoming role players in a system of someone else's design. In order to prevent the latter scenario from becoming a self-fulfilling prophecy, physician leaders need to educate themselves about the changing medical marketplace and be prepared to take decisive action."

Mr. Miller's article was entitled, "The Way Forward? Mounting Pressures on hospitals and physicians both suggest that new models of working may be the way of the future" and was published in the Southern California Physician (September 2010). The complete article can be found at: <a href="www.socalphysician.net/past\_features/2010/09/hospital-physician-alignment-the-way-forward">www.socalphysician.net/past\_features/2010/09/hospital-physician-alignment-the-way-forward</a>

#### **Medical Directorships**

A medical directorship is largely a generic or catch-all phrase used to describe a physician who has contracted with a hospital to have responsibility for the medical direction of a department or other unit or service within the hospital. Duties for medical directors vary, depending on the agreement and can range from recruiting, attending meetings, conducting clinical peer reviews, research, training and participating strategic development.

#### **Call Coverage Agreements**

Many hospitals enter into agreements with specialty physicians to secure the availability for on-call coverage in the emergency department so that the hospital is able to meet its obligations under the Emergency Medical Treatment and Active Labor Act ("EMTALA"). (42)

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Department of
Managed Health Care
Orders Anthem Blue
Cross to Pay Health
Care Providers for
Services Dating Back
to 2007

In 2008, DMHC launched provider claims audits of the seven largest health plans in California due to the growing pattern of complaints from providers regarding late and inaccurate payments and inappropriate claims denial.

To date, the other six health plans have taken steps to repay providers.

But not Anthem Blue Cross.

DMHC has given Anthem Blue Cross 30 days to file a plan to bring them into compliance and to identify the claims that were not paid correctly and pay the providers as prescribed by law. U.S.C. §1395dd.) While payments under the agreement may raise fraud and abuse concerns, the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services has provided significant guidance as to how payments for on-call coverage might comply with the federal anti-kickback prohibition. For further information, see "Enhancing Your Practice's Revenue: Pearls and Pitfalls," American Academy of Orthopedic Surgeons/American Association of Orthopaedic Surgeons (2011), Chapter 7, which can be found at http://www3.aaos.org/member/prac\_manag/enhancing\_revenue\_primer.pdf.

#### **Specialty Hospitalists**

In addition to the "legacy" hospitalist fields of adult and pediatric medicine, specialties such as neurology, orthopaedics, and others are, in some settings, choosing to organize themselves into a hospitalist model of practice. When using specialty hospitalists, hospitals typically reallocate the dollars spent on call coverage to instead support a hospitalist practice in that specialty. Hospitals also use these physicians to support the hospital's quality of care goals and other initiatives.

#### **Service Line Co-Management**

This model will be highlighted at COA's 2012 Annual Meeting. Hospitals often use service line co-management agreements to contract with medical groups to manage a clinical service line operated by the hospital, but again there is tremendous variation in the scope of services that are to be provided under this model. Thus, in addition to or as an alternative to clinical oversight and protocol development, some agreements call for developing capital and operating budgets, providing staff and community outreach/education, selecting personnel and equipment, training non-physician staff, etc.. Typically, the hospital pays either the medical group or a management company (which can be wholly or partially physician-owned) a fair market fee for the services provided under the agreement. A performance-based payment sometimes is made where specified quality, patient satisfaction and operational goals are met. For further information, see "Enhancing Your Practice's Revenue: Pearls and Pitfalls," American Academy of Orthopedic Surgeons/American Association of Orthopaedic Surgeons (2011), Chapter 9, which can be found at <a href="http://www3.aaos.org/member/prac manag/enhancing revenue primer.pdf">http://www3.aaos.org/member/prac manag/enhancing revenue primer.pdf</a>.

#### **Pay-for-Performance Agreements**

Similar to service line co-management agreements, pay-for performance agreements can result in financial rewards to physicians for their efforts to improve service at a specific hospital, such as by avoiding central line infections and reducing re-admissions. Unlike service line co-management agreements, however, these agreements do not compensate physicians for management services, but instead financially incentivize physicians to take steps to help the hospital achieve higher scores on designated quality metrics. More information on these arrangements can be found at http://www.aaos.org/news/bulletin/aug07/managing4.asp.

#### **Physician-Owned Distributers (PODs)**

With PODS, physician-owned entities sell items such as orthopaedic implants, to hospitals. Proponents of PODs believe that these such arrangements result in savings to hospital and payors, increase the quality of products utilized and promote physician-hospital alignment. Opponents are concerned that costs will increase as PODs control more of the market and medical decision-making will be influenced by financial gain. As with all physician-hospital relationships, there are considerable regulatory risks as was covered in the December, 2011 Cal Ortho On-Line which can be found on COA's website: www.coa.org The OIG will study PODs as part of its 2012 work plan. Further regulation of PODs is expected. For a copy of the 2012 OIG Work Plan, go to: <a href="http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current">http://oig.hhs.gov/reports-and-publications/workplan/index.asp#current</a>

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#### Joint Ventures

Joint ventures between physicians and hospitals take many forms but are generally characterized by joint funding, sharing of profits and losses, and common control of resources by the participants. They frequently provide health services through an ambulatory surgical center, specialty center or independent testing diagnostic facility, but also may restrict their scope to the provision of management or leasing arrangements (i.e., the jointly owned company manages the physician/group practice or leases equipment to the hospital.) While joint ventures are attractive to many, special care must be taken to avoid application of the fraud and abuse law. For further information, attend COA's Annual Meeting where this model will be discussed and also refer to, "Enhancing Your Practice's Revenue: Pearls and Pitfalls," American Academy of Orthopedic Surgeons/American Association of Orthopaedic Surgeons (2011), Chapter 8, which can be found at <a href="http://www3.aaos.org/member/prac manag/enhancing revenue primer.pdf">http://www3.aaos.org/member/prac manag/enhancing revenue primer.pdf</a>.

#### **Management Service Organizations (MSOs)**

Under this model, hospitals, either alone or in conjunction with a physician-owned organization, owns and operates a MSO to provide practice management and administrative support to individual physicians or group practices. Often in these arrangements, the medical practice sells its non-professional assets (medical equipment, supplies, property, etc.) to the management company.

#### Affiliated (or Physician-Friendly) Professional Corporation

In this model, a hospital selects a physician to serve as the sole share shareholder of the professional medical corporation. Generally speaking, this physician would have a pre-existing relationship with the hospital, such as a medical directorship or other executive position. There typically will be a number of agreements defining the parties' respective rights and obligations. For example, the physician, professional corporation and hospital would enter into a shareholder agreement whereby the physician agrees to seek the hospital's approval before taking certain actions, such as transferring shares, declaring dividends, etc.. The professional corporation would enter into employment agreements with physicians to provide medical care. The hospital also would typically manage the professional corporation through a management services agreement. In the end, these contracts grant the hospital some control over the professional corporation's practice. According to the Healthcare Financial Management Association, "the distinguishing feature of this model is the high level of control" the lay entity "exerts over the friendly physician's role and responsibilities." *See* Bigalke, et al. "Consolidation Guidelines for Physician Practices," Health Management, March 1998. Go to: <a href="http://findarticles.com/p/articles/mim m33257/is n3 v52/ai 20633697/?tag=content;col1">http://findarticles.com/p/articles/mim m33257/is n3 v52/ai 20633697/?tag=content;col1</a>

#### **Gainsharing Arrangements**

Gainsharing is an arrangement between physicians and a hospital that allows them to share in any savings in a particular hospital service line obtained through the physicians' participation in the medical management of that service line. According to the OIG's 1999 Special Advisory Bulletin:

"In most arrangements, in order to receive any payment, the clinical care must not have been adversely affected as measured by selected quality and performance measures..."

There have been a number of favorable OIG opinions regarding specific gainsharing arrangements that included safeguards against the risk of a kickback violation, such as incentive caps, volume-neutral compensation formulas and per capita (rather than admission-based) distributions. OIG Advisory Opinion, No. 08-09, conditionally approved a gainsharing arrangement between a hospital and groups of orthopaedic and neurosurgeons that distributed

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savings achieved through cost reduction measures involving certain medical equipment and supplies used during spinal fusion surgery. The OIG Special Advisory Opinions and Special Bulletin can be found on the OIG website under the "Compliance" section at <a href="https://www.oig.hhs.gov">www.oig.hhs.gov</a>.

#### **Bundled Payments**

In a bundled payment methodology, a single, "bundled" payment covers services delivered by two or more providers, usually including physicians and hospitals, during a single episode of care or over a specific period of time. As an example, if a patient has hip replacement surgery, rather than making one payment to the hospital, a second payment to the surgeon and a third payment to the anesthesiologist, the payer would combine these payments for the specific episode of care (i.e., hip replacement surgery). In an article published by AAOS, it was reported that a group of orthopaedic physicians and Hoag Hospital in Newport, California developed a bundled payment system. For more information, see *Hospital-physician alignment: Passing trend or a new paradigm?* Jacque Roche Buschmann and Kevin J. Bozic, MD, MBA, a copy which can be found at http://www.aaos.org/news/aaosnow/oct09/reimbursement3.asp.

In addition, physicians do not need to be in large groups in order to bundle payments. In fact, in 2009, the Medicare Acute Care Episode Demonstration Project paid a number of Physician-Hospital Organizations (PHOs) a single "bundled" payment for, among other types, nine orthopedic procedures. The orthopaedic surgeons at one at the PHOs, Hillcrest Medical Center in Tulsa, Oklahoma were independent physicians. For more information, *see* "Pathways for Physician Success Under Healthcare Payment and Delivery Reforms," Harold D. Miller, American Medical Association (June 2010) at: <a href="http://chapteraffairs.acc.org/BOGUpdate/Documents/Payment-pathways\_HMiller.pdf">http://chapteraffairs.acc.org/BOGUpdate/Documents/Payment-pathways\_HMiller.pdf</a>

Significantly, the Centers for Medicare & Medicaid Services (CMS) is inviting healthcare providers to apply to help test and develop four different models of bundling payments through its Bundled Payments Initiative. While they are no longer accepting applications for model one (inpatient stay only), applications for the Bundled Payments for Care Improvement Models 2-4 (relating to inpatient and post-acute care, and prospective payment bundling) are due on April 30, 2012. For more information, visit the CMS website at <a href="http://innovations.cms.gov/initiatives/bundled-payments/">http://innovations.cms.gov/initiatives/bundled-payments/</a>.

#### **Hospital Outpatient Department Clinics-1206(d)**

Hospital outpatient department clinics that operate under a hospital's license are exempt from obtaining a separate license under Health & Safety Code Section 1206(d). A hospital outpatient service can provide orthopaedic services as it is defined under the hospital licensing regulations as "the rendering of nonemergency health care services to patients who remain in the hospital less than 24 hours with the appropriate staff, space, equipment and supplies." 22 CCR 70525. A 1206(d) outpatient department clinic can be located in the main hospital or in a free-standing building on or off the hospital's main campus. It should be noted that in addition to the general legal requirements applicable to most physician-hospital partnership models, outpatient department clinics are licensed as supplemental services of the hospital and; therefore, must meet many specific hospital licensure requirements.

A physician typically affiliates with an outpatient clinic through a professional services agreement with the hospital. This agreement defines the responsibilities of the parties. The physicians are obligated to provide services at the hospital. In some cases, the hospital may provide billing, collection and other practice support services to the physicians staffing the clinic. In addition, the hospital may also purchase the assets of the medical practice and convert the physicians' offices into an outpatient department of the hospital.

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#### **Medical Foundations.** – 1206(l)

Like hospital outpatient department clinics, medical foundations are statutorily exempt from obtaining a clinic licensure pursuant to Health & Safety Code Section 1206(l). To fall within that exemption, the foundation must:

- be operated by a non-profit corporation exempt from the federal income taxation under Paragraph (3) of Subsection (c) of Section 501 of the Internal Revenue Code,
- conduct medical research and health education,
- provide health care to its patients through a group of 40 or more physicians and surgeons who are independent contractors, and not less than two-thirds of whom practice on a full-time basis at the clinic, and
- ensure the physicians represent not less than 10 board certified specialties.

Significantly, because a foundation must be a non-profit corporation that is exempt from licensure, it cannot be "owned" by a hospital. Some hospitals, however, create a tax-exempt corporation to serve as the medical foundation that owns and operates the clinic. In such a case, the hospital plays a significant role in the affairs of the foundation.

To provide care to its patients, the foundation enters into an agreement with one or more medical groups. The physicians remain employees of the medical group, not the foundation. The foundation usually owns the medical facilities and equipment and hires the non-physician employees. In addition, the foundation, not the medical group, negotiates, enters into and receives the payments pursuant to managed care contracts. The medical foundation bills payors for services, and then compensates its contracted medical group.

As of 2010, there were at least 17 medical foundations in existence in California that provided care to a total of 8,369 patients through 2,662 primary care physicians and 5,707 specialists. See Witt M.S.W., Mary etal, "*Physician-Hospital Integration in the Era of Health Reform,*" California HealthCare Foundation (December 2010). Go to: <a href="http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/P/PDF%20PhysicianHospitalIntegrationEraHealthReform.pdf">http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/P/PDF%20PhysicianHospitalIntegrationEraHealthReform.pdf</a>

#### **Accountable Care Organizations**

An accountable care organization (ACO) is a group of providers (which can allow a hospital to be a participant) who join together to coordinate care, share clinical information and report on quality measures. Participants share in any cost savings they receive as a result of their efforts. Given the rapidly changing health care environment, ACOs can take many shapes and forms. Indeed, many of the partnerships described above, with their ability to obtain and share savings based on system improvements are really ACO-type agreements but on a more limited scale. Accordingly, many "private ACOs," loosely defined, are operating in the commercial market-place set up by group health insurers.

On November 2, 2011, the Medicare program released its final rules detailing the requirements for entities that wish to participate as a Medicare ACO in its shared savings program. The rules span 189 pages in the Federal Register and impose a number of detailed quality, organizational, financial and reporting obligations on organizations wishing to participate as an ACO. A copy of these regulations can be found at <a href="http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf">http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/pdf/2011-27461.pdf</a>. Medicare will be accepting applications from organizations in 2012. Information on how to apply can be found at:

https://www.cms.gov/sharedsavingsprogram/37 Application.asp#TopOfPage.

In the meantime, on December 19, 2011, Medicare announced the names of 32 organizations, 6 from California, that are eligible to participate in its "Pioneer ACO" initiative. According to

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Partnerships

Your Input

COA wants to hear from you so that *Cal Ortho On-Line* can be of the most value to its members.

Please let us know of any issues that you would like to see addressed or other ideas for inclusion in future editions.

Comments can be forwarded to:

coa1@pacbell.net

CMS, the Pioneer ACO program is designed to reward early adopters of coordinated care models. Medicare estimates that it could save up to \$1.1 billion over five years with this model. The six California organizations selected to take part in the Pioneer ACO initiative are:

- Brown & Toland Physicians, based in San Francisco;
- HealthCare Partners Medical Group, which serves Los Angeles and Orange counties;
- Heritage California ACO, which serves southern, central and coastal California;
- Monarch HealthCare, based in Orange County;
- PrimeCare Medical Network, which serves Riverside and San Bernardino counties; and Sharp HealthCare System, based in San Diego

For more information, see <u>www.californiahealthline.org/articles/2011/12/20/six-calif-entities-are-pioneer-accountable-care-organizations.aspx#ixzz1jqV0fSBr.</u>

#### **Employment**

Notwithstanding the prohibition against hospital's employing physicians (see discussion below), even hospital employment of physicians can be an option. Under the law, certain entities, such as the University of California, a staff model HMO, the government and community clinics, may employ physicians for the provision of medical care. In addition, all hospitals may employ physicians for non-patient care activities in administrative capacities, such as a medical director, chief medical officer, risk management director, etc..

As can be seen from the above discussion, there is no shortage of options to consider when contemplating a physician-hospital partnership. However, not every option is for every physician and physicians are urged to work with an experienced advisor to decide whether such a partnership makes sense from a practical and financial perspective. Physicians who are contemplating a relationship with a hospital are further cautioned that the legal landmines concerning these arrangements are significant and that the advice of an attorney experienced in this area is essential

## THE LEGAL LANDMINES OF PHYSICIAN-HOSPITAL PARTNERSHIPS

Just as there is no shortage of models for physicians and hospitals to consider when deciding upon an organizational option, there is no shortage of laws that must be complied with when structuring the arrangement. Both the state and federal governments have been very active in making and enforcing laws designed to protect independent medical decision-making and patients from inappropriate utilization of health care services. In addition, depending upon the size of the combined organization and tax status of the entity, antitrust and tax-exemption issues often come into play in physician-hospital partnerships.

The discussion below is intended to give a general overview, or bird's eye view, on the relevant laws. It cannot be emphasized enough, however, as simple as these laws may appear in this discussion, they are very complicated and can be enforced by not only state and federal enforcement agencies, but also by whistleblowers, such as private competitors, under state and federal False Claims Acts. Consequently, all eyes are on physician-hospital partnerships, making it imperative that any arrangements be carefully reviewed by an attorney experienced in this area, be reduced to writing and be set at terms that reflect the fair market value of the good and services to be provided under the arrangement.

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#### **The Corporate Practice of Medicine Bar**

California's strong corporate practice of medicine bar contains a significant protection against the possibility that a physician's judgment in the provision of medical care will be compromised by a lay entity, either directly or indirectly. See Business & Professions Code §§2052 and 2400. Pursuant to this law, a license to practice medicine may be issued only to a properly licensed person, not to a corporate entity and with very narrow exceptions, lay (non-physician) entities may not contract with or employ physicians for the provision of medical care. 63 Ops.Cal.Atty.Gen. 729 (1980) (for-profit corporations may not engage in the practice of medicine directly nor may it hire physicians to perform professional services); (65 Ops.Cal.Atty.Gen. 223 (1982) (general business corporation may not lawfully engage licensed physicians to treat employees even though physicians act as independent contractors and not as employees).

Hospitals are lay entities subject to Section 2400. (11 Ops.Cal.Atty.Gen. 236 (1948) (private non-profit hospital may not employ physicians and charge patients for physician services); (54 Ops.Cal.Atty.Gen. 126 (1971) (hospital may not employ a physician to provide emergency service, even if a hospital charges for professional services in an amount proportionate to the physician's salary). Consequently, hospitals may not employ or contract with physicians for the provision of medical care, unless an exception exists, such as is the case for government and University of California hospitals.

There are numerous Attorney General and judicial determinations upholding the corporate bar broadly to encompass its protective purpose by recognizing that the practice of medicine involves both clinical and business implications. These opinions prohibit hospitals not only from employing and/or contracting with physicians to retain their profession fees, but also from managing their practices in a manner that exerts too much dominion and control over their practice. Thus, for example, a lay entity may not have a financial interest in a medical practice's bottom line and where a lay entity sets a physician's fees, or has any control over the receipt and collection of such fees, including but not limited to, through the negotiation and management of managed care contracts, it is practicing medicine in violation of the Business & Professions Code §2400. See, for example, 55 Ops.Cal.Attv.Gen. 103 (1972) (an agreement between a physician and a hospital constituted the unlawful practice of medicine where, among other things, the physician neither set his own fees nor had any control over the receipt and collection of such fees). See also 83 Ops.Cal.Atty.Gen. 170 (2000) (concluding that a management service organization paying for radiology services and profiting by adding a fee for its own management services further intrudes into the physician/ patient relationship) and 92 Ops.Cal.Atty.Gen. 56 (2009) (lay entity charging and collecting for radiology services violates corporate bar.)

The Medical Board of California similarly understands the breadth of the corporate bar and has developed a succinct Guidance for interested persons to review when considering arrangements with lay entities. From the Medical Board's perspective, the following "business" or "management" decisions and activities resulting in control over the physician's practice of medicine should be made by a physician licensed in the State of California and not by an unlicensed person or entity:

- Ownership is an indicator of control of a patient's medical records, including determining the contents thereof, and should be retained by a California licensed physician.
- Selection (hiring/firing as it relates to clinical competency or proficiency) of professional, physician extender, and allied health staff.
- Setting the parameters under which the physician will enter into contractual

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relationships with third-party payers.

- Decisions regarding coding and billing procedures for patient care services.
- Approval of the selection of medical equipment for the medical practice.

A full copy of the Medical Board Guidance may be found at <a href="www.mbc.ca.gov">www.mbc.ca.gov</a>. In summary, the Medical Board Guidance, as well as all relevant laws regarding the corporate bar, must be carefully reviewed in conjunction with any proposed physician-hospital relationship.

#### Fraud and Abuse

There are literally scores of fraud and abuse provisions applicable to physician—hospital partnerships that go beyond the scope of this discussion. Indeed, financial relationships between hospitals and physicians have come under even more increased scrutiny recently-due to a rise in whistleblowers reporting violations in hospitals and stricter enforcement of the anti-kickback statute, the self-referral law, and the False Claims Act. Numerous exceptions to these laws exist, but any financial relationships between physician and hospitals must be carefully structured to meet these exceptions, when, and where necessary.

#### Anti-kickbacks and Self-Referrals.

Both California and federal law prohibit kickbacks and fee splitting by physicians and other health care providers. California's general prohibition, Business & Professions Code §650, provides in pertinent part:

"...the offer, delivery, receipt or acceptance, by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person..., is unlawful."

As with California law, Federal Medicare and Medicaid law similarly prohibit "feesplitting." (42 U.S.C. §1320a-7b(b).) Simply stated, these laws prohibit the payment of any remuneration (basically anything of value) in exchange for the referral of patients and apply only if one purpose of the arrangement is to induce referrals. See *United States v. Kats* (9th Cir. 1989) 871 F.2d 105 (holding that it is not a defense that there might have been reasons other than referral of patients for a payment). Violations of these laws carry hefty fines and penalties, including imprisonment.

Physician referral of patients for specified goods or services in which the physician or physician's immediate family has a financial interest is also restricted by both federal and California law. In general, the federal self-referral law (Stark I–relating to clinical laboratory services, and Stark II–relating to additional "designated health services" (DHS)) prohibits a physician from making a referral to an entity for the provision of designated health services (including hospital inpatient and outpatient services) *if* the physician has a financial relationship with the entity. (42 U.S.C. §1395nn.) If the ban applies, the physician may not make a referral to the entity for DHS which may be paid for by Medicare or Medicaid *and* the entity may not, directly or indirectly, bill for any DHS resulting from a prohibited referral to any individual, third party payor, or other entity. California also broadly prohibits physician self-referral of patients. *See* Physician Ownership & Referral Act of 1993 (PORA), Business & Professions Code §§650.01, 650.02.

Recognizing that not all arrangements between physicians and hospitals are illegal, the federal government developed a number of "safe harbors" and exceptions to the anti-kickback and self-referral laws that provide significant latitude for the parties. They cover

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a wide range of situations and provide considerable relief when entering into the models described above. Physicians can access the regulations providing for these "exceptions" at <a href="http://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp">http://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp</a>.

As can be seen, fulfilling the elements for compliance can be complicated. For example, for an agreement to come within the personal services "safe harbor" to the anti-kickback statute:

- 1) The agreement must be set out in writing and signed by the parties;
- 2) The contract covers all of the services to be provided for the term of the agreement;
- 3) The arrangement has a term of at least one year;
- 4) The compensation is consistent with fair market value in arms length transactions and is not determined in a manner that takes into account the volume or value of referrals or business otherwise generated, except in the case of a physician incentive plan described below;
- 5) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law;
- 6) The aggregate compensation paid over the term of the agreement is set in advance; and
- 7) If the agreement is intended to provide for services on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length and the exact charge for such intervals. See 42 C.F.R. 1001.952.

A failure to meet these requirements may very well result in battle with the OIG and others. Physician –hospital arrangements are frequently the target of anti-kickback and self-referral allegations as many have accused them to be nothing more than a disguised payment for a referral. In fact, in 2011 alone, the Office of the Inspector General for the U.S. Department of Health and Human Services (OIG) has settled cases with hospitals challenging the following practices that resulted from physician-hospital arrangements:

- Failing to collect rental payments. See The Charles Town General Hospital dba Jefferson Memorial Hospital, and West Virginia University Hospitals-East, Inc. (11/29/11)
- Providing incentives for physicians to refer patients to hospital in call coverage agreement. County of Monterey dba Natividad Medical Center (NMC), California (10/04/11).
- Providing spaces, services and supplies without a written agreement and without collecting payment. Westfields Hospital, Wisconsin (10/03/11).
- **Failing to renew or enter into written contracts for physician services.** Whidbey Island Hospital District (WIHD), Washington (09/08/11).
- **Paying too much for services.** Good Samaritan Hospital Medical Center (GSHMC), New York (07/13/11); St. Catherine of Siena Medical Center (St. Catherine), New York (07/13/11).
- **Paying for services that were never rendered.** Pacifica Hospital of the Valley (Pacifica), California (05/11/11).
- Failing to enter into written lease agreement with a physician practice. Fairview Northland Regional Health Care (FNRHC), Minnesota (03/24/11)

And these are just the cases that were settled by the OIG in 2011. The numerous cases settled by the OIG from prior years can be found on the OIG website. See <a href="http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp">http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp</a>. The above illustration does not even begin to cover the litany of lawsuits brought by not only the OIG, but also private parties under the False Claims Act.

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**Unlawful Physician Incentive Plans/Gainsharing.** A physician who knowingly accepts a payment made as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries may face a civil monetary penalty of up to \$2,000 for each such payment received. (42 U.S.C. §1320a-7a(b)(2).) As mentioned above, the OIG has issued a number of advisory opinions favorable to gainsharing arrangements that can be found on the OIG website under the "Compliance" section at <a href="www.oig.hhs.gov">www.oig.hhs.gov</a>.

**False Claims.** Physicians face civil money penalties for knowingly presenting any claim that is for, among other things,

- (1) an item or service that the person knows or should know was not provided as claimed, or
- (2) a medical or other item of service and the person knows or should know that the claim is false or fraudulent. (42 U.S.C. §1320a-7a(a)(1)(A)-(C).)

Physicians should understand that this law does not require actual knowledge of the falsity of the claim: a finding that the physician "should have known" is enough for a finding of liability. Under these circumstances, compliance with this law can be particularly tricky with respect to the submission of claims, to the Medicare program, particularly given the complexity of the rules.

#### Antitrust

Even the antitrust laws come into play where physicians and hospitals integrate. The basic objective of the antitrust laws is to protect the free market. As a result, the antitrust laws generally prohibit contracts, combinations, conspiracies and restraint of trade, or single entities which become so large that they attempt to become or, in fact, are a monopoly. See 15 U.S.C. §§1, 2. Antitrust laws can arise, for example, if a physician-hospital alliance becomes so large, it is in essence exercising substantial market power in the relevant area. (Market power is present when the entity has the power to control prices or exclude competition in the market). Courts have allowed antitrust lawsuits against a hospital and its "affiliated medical group" to proceed under this theory. See *Perinatal Medical Group v. Children's Hospital* (E.D.Cal 2010) 2010 WL 1525511. Similarly, to the extent a hospital and physician organization are otherwise competing organizations, the arrangement between them could conceivably be challenged as a restraint of trade unless they are sufficiently integrated for the purposes of the antitrust laws.

#### **Internal Revenue Service: Tax Exemption Issues**

Tax laws are implicated where the hospital, or its sponsored medical foundation, is tax exempt pursuant to Internal Revenue Code (IRC) §501(c)(3). Health care issues have received priority by the IRS enforcers for a number of years and with respect to physicians, the greatest implication of this issue is on their compensation. Accordingly, physicians are strongly urged to consult with qualified legal counsel because the requirements for qualification and maintenance of Section 501(c)(3) tax-exempt status are extremely detailed and complex.

In general, in order to qualify for tax exemption under IRC Section 501(c)(3), an entity must be organized and operated exclusively for charitable purposes, with no part of its earnings inuring to the benefit of a private shareholder or individual. The IRS looks to a number of factors when evaluating the qualifications of a health care organization for tax exemption. The following list, while not exhaustive, illustrates the type of factors that the IRS will consider in this regard.

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Community Board: The board of directors/trustees must consist of individuals who are independent of the sponsoring organization and representative of the community. The independent representatives must comprise the majority of the board. Practicing physicians affiliated with the health care organization, corporate executives, department heads and other facility employees are not considered independent due to their close and continuing connection with the facility. While they may serve on the board, they may not comprise a majority.

**Charity Care:** The health care organization must show a commitment to provide health care to members of the community. Participation in the Medicare and Medicaid programs is regarded by the IRS as a key factor in establishing that commitment. Charity care, too, is relevant and the IRS will expect the health care organization to formally adopt and implement a charity care policy that is made known to the public. This policy should confirm, among other matters, that patients will receive health care services based on ability to pay.

Medical Training, Research and Other Health Related Activities: The IRS believes that commitments to medical training or research are ways that the health care organization can demonstrate its commitment to serve the needs of the community. The health care organization can further demonstrate that commitment through the following activities: free health education programs (e.g., cardiac information and pregnancy counseling), seminars (e.g., stop smoking) or community health fairs.

**Reasonable Compensation:** The IRS requires assurances that the health care organization compensates its employees and independent contractors at reasonable amounts, and that the terms of the arrangements (e.g., leases, service contracts and vendor agreements) with other third parties comport with fair market value principles, so that the funds of the organization do not inure to the benefit of private interests. For additional guidance, please see IRS, Hospitals, Clinics and Similar Health Care Providers Reference Guide, attached to August 3, 2006 Memorandum for Manager, EO Determinations, a copy of which can be located at www.irs.ustreas.gov/pub/foia/ig/tege/tege 07 0806 04.pdf.

Significantly, Congress has been so concerned that tax-exempt organizations were not meeting their charitable mission that the Secretary of the Treasury or his or her delegate, i.e., the Internal Revenue Service (IRS), must review at least once every 3 years the community benefit activities of each tax-exempt hospital. (26 U.S.C.A. §4959.)

Affiliating with a hospital is an option that many physicians will consider. But physicians, with the assistance of independent advisors, must proceed very cautiously to ensure that their legitimate interests are protected. Accordingly, physicians are urged to seek the advice of a health care attorney experienced in these matters when considering such a partnership.

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Instructional
Course —
Advanced
Ultrasound
Techniques

Will be presented at COA's 2012 Annual Meeting/QME Course— April 19-22, 2012 Park Hyatt Aviara Resort

Go to: www.coa.org to register for the meeting.

COA members have expressed an interest in learning about the use of ultrasound in making an orthopaedic diagnosis. COA has held a series of basic MSK Ultrasound courses to allow our members to evaluate its use and application in their practice.

COA will be offering an ultrasound course at our 2012 Annual Meeting/QME Course. This course will focus on advanced ultrasound techniques and include a cadaver lab on performing orthopaedic injections using ultrasound. Go to: www.coa.org to register for the meeting.

Below is a reprint of an "Information Sheet" from SonoSite to help our members better understand the ultrasound reimbursement issues. COA is in no way endorsing the recommendations in this article. It is provided only for your information.

January 2011

#### **Ultrasound Reimbursement Information**



This guide provides general information for ultrasound reimbursement. SonoSite provides this information as a courtesy to assist providers. It is the provider's responsibility to determine and submit appropriate codes, modifiers, and claims for services rendered. SonoSite makes no guarantees concerning reimbursement or coverage. Please feel free to contact the SonoSite reimbursement staff if you have any questions at 1-888-482-9449 or send email to reimbursement@sonosite

## 1. What are the requirements for image documentation and reporting?

All diagnostic ultrasound examinations, including those when ultrasound is used to guide a procedure, require that permanently recorded images be maintained in the patient record. The images can be maintained in the patient record or some other archive – they do not need to be submitted with the claim. Images can be stored as printed images, on a tape or electronic medium. Documentation of the study must be available to the insurer upon request.

A written report of all ultrasound studies should be maintained in the patient's record. In the case of ultrasound guidance studies, the written report may be filed as a separate item in the patient's record. Ultrasound guidance procedures also require permanently recorded images of the site to be localized, as well as a documented description of the localization process, either separately or within the report of the procedure for which guidance is utilized.

# 2. I am a physician, but not a radiologist; will I get reimbursed for providing ultrasound services?

Private insurance payment policies vary by payer and plan with respect to which specialties may perform ultrasound services.

Some payers may restrict imaging procedures to specific specialties or providers with specific credentials only. Contact your private payers before submitting claims to determine their requirements and request that they add ultrasound to your list of services.

Medicare does not differentiate by medical specialty with respect to billing medically necessary diagnostic ultrasound services, provided the services are within the scope of the physician's license. Some Medicare carriers require that the physician who performs and/or interprets some types of ultrasound examinations be capable of demonstrating relevant, documented training through recent residency training or postgraduate CME and experience. Contact your Medicare Part B Carrier for details.

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# Instructional Course — Advanced Ultrasound Techniques

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Go to: www.coa.org to register for the meeting.

CalOrtho On-Line is provided as a benefit to assist COA members in being informed and understanding practice management changes and other issues affecting their medical practice.

It does not and should not be construed to constitute legal advice.

COA members in need of legal assistance are urged to retain the services of an attorney experienced in health care law.

3. When I contact my private payers, what do I ask the Provider Representative to determine whether or not I can obtain payment for ultrasound services?

You need to ask the following questions (Have the list ready of ultrasound codes you will be reporting.)

- What do I need to do to have ultrasound added to my practice's contract or list of services?
- Are there any specific training requirements that I must meet or credentials that I must obtain in order to be privileged to perform ultrasound in my office?
- Do I need to send a letter or can I submit the request verbally?
- Is there an application that must be completed?
- If there is a privileging program, how long will it take after submission of the application before we are accepted?
- What is the fee schedule associated with these codes?
- Are there any bundling edits in place covering any of the services I am considering performing? (Be prepared to provide the codes for any non-ultrasound services you will be performing in conjunction with the ultrasound services.)
- Are there any preauthorization requirements for specific ultrasound studies?

## 4. Do I need to add any modifiers to the ultrasound codes for services provided in my office?

No modifiers are required for ultrasound studies performed in your office. In the office setting, a physician who owns the equipment and performs both components of the service him or herself or through an employed or contracted sonographer may report the global service, which is represented by the CPT code without any modifiers.

# 5. What if a diagnostic ultrasound is performed followed by an ultrasound guided procedure, can both codes be reported for the same patient same date?

It will depend on the situation. Per the Radiology section of the National Correct Coding Initiative (NCCI):

"Ultrasound guidance and diagnostic ultrasound (echography) procedures may be reported separately only if each service is distinct and separate. If a diagnostic ultrasound study identifies a previously unknown abnormality that requires a therapeutic procedure with ultrasound guidance at the same patient encounter, both the diagnostic ultrasound and ultrasound guidance procedure codes may be reported separately. However, a previously unknown abnormality identified during ultrasound guidance for a procedure should not be reported separately as a diagnostic ultrasound procedure."

# 6. What if more than one aspiration or injection is guided with ultrasound on the same patient same date?

National Correct Coding Initiative also provides the following on multiple procedures – CPT code 76942 is the ultrasound guidance of injections:

"CPT codes 76942, 77002, 77003, 77012, and 77021 describe radiologic guidance for needle placement by different modalities. CMS payment policy allows one unit of service for any of these codes at a single patient encounter regardless of the number of needle placements performed. The unit of service for these codes is the patient encounter, not number of lesions, number of aspirations, number of biopsies, number of injections, or number of localizations."

The information in this handout is intended to assist providers in determining appropriate codes and the other information for reimbursement purposes. It represents the information available to SonoSite as of the date listed above. Subsequent guidance might alter the information provided. SonoSite disclaims any responsibility to update the information provided. The only persons authorized by SonoSite to supply information regarding any reimbursement matter not reflected in a circular such as this are members of SonoSite's reimbursement staff.