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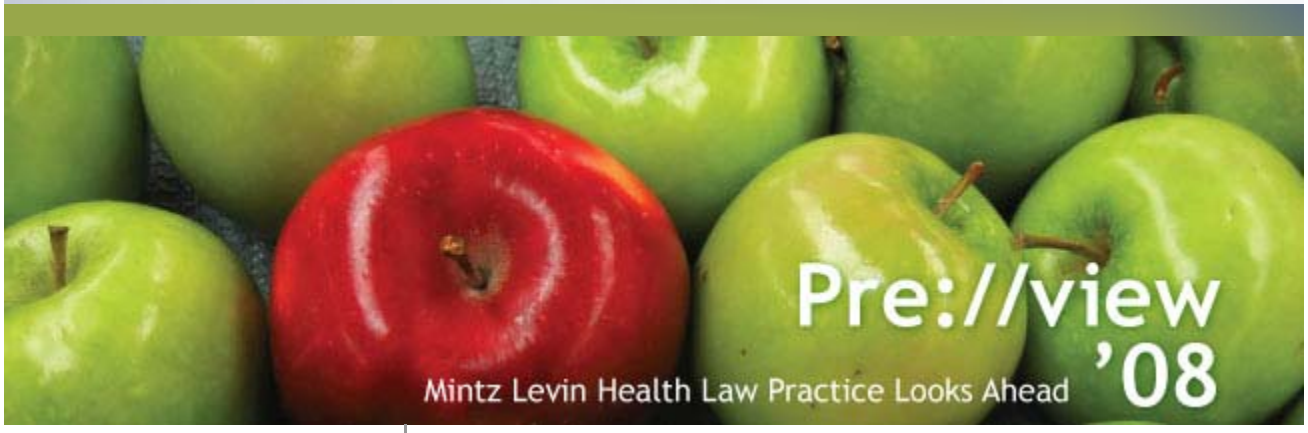

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Being Prepared Is the Best Defense

"Give me insight into today and you may have the antique and future worlds." Ralph Waldo Emerson had it right: To understand current events, you must be aware of preceding developments, and, in doing so, you can better prepare for the future. Mintz Levin's Health Law Practice believes that an in-depth grasp of the issues driving the health industry must be grounded in their history, and only then can those insights inform legal and business strategies going forward.

We therefore have assembled the following overview of a few significant issues and developments that have recently become prominent in the health industry and that certainly will continue to take center stage in the coming year.

Steve Weiner, Chair of Mintz Levin's Health Law Practice, describes the 2008 outlook as follows: "Government enforcement will continue in intensity and will affect major structuring decisions in the fields. On a more positive note, we have reached an exciting and challenging intersection of technological innovation and services delivery. How new technologies are used, and how the law facilitates or impedes their application, have enormous implications for the cost, quality, and accessibility of care. These are key developments to watch in 2008 and beyond."

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Buzz Around "Never Events" Continues

The Centers for Medicare & Medicaid Services (CMS) announced last August that, as of October 2008, it will no longer allow reimbursement to hospitals for certain preventable medical conditions. This list includes bed sores, fractures from falls, urinary tract infections from catheters, and three of the twenty-eight "never events" identified by the National Quality Forum (NQF).

Large private insurance companies are following suit and banning payment for the most egregious medical errors identified by NQF, including operating on the wrong limb or performing the wrong surgical procedure. Aetna is beginning to stipulate in hospital contracts that it will not cover the cost of care for the twenty-eight "never events" while WellPoint is testing the waters with four errors from the NQF list. UnitedHealth Group, CIGNA, and Humana are also exploring policies inspired by Medicare.

> **We can expect "never events" policies to become an increasingly common fixture in the reimbursement landscape of American healthcare and likely will require hospitals and, possibly, other providers to institute systems and technologies intended to eliminate all such events.**

Minnesota and Massachusetts have become the only states in the nation to mandate that all hospitals adopt a uniform policy of not charging patients or insurers for NQF's serious errors. The Massachusetts Hospital Association (MHA) played a lead role in encouraging its member hospitals voluntarily to accept the new policy, which codifies long-standing safety practices and strengthens hospital commitments to preventing adverse medical events. "Under current practice, in the extremely rare case that a serious adverse event does occur, Massachusetts hospitals disclose the incident and apologize to the patient. Additionally, hospitals report the incident to separate programs at the Massachusetts Department of Public Health and the Board of Registration in Medicine," explains Ellen Janos.

MHA expects to issue its "never events" policy in early 2008 and to cover events such as wrong site surgery, surgery on the wrong patient, wrong surgical procedure, and unintended retention of a foreign object. MHA

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will collaborate with an advisory group of hospital members from the clinical and financial areas, the physician community, health insurance companies, and patient-consumer representatives.

One Size Does Not Fit All…

"Stand in the Shoes" Provisions Call for Swift Attention

Despite the Stark Phase III regulations coming into effect on December 4, 2007, the health industry will need time to sort through the requirements and impact of these new regulations, says Tom Crane. But the new "stand in the shoes" provisions demand immediate attention from certain hospitals—especially from nonacademic medical centers and freestanding hospitals that are not part of a tax-exempt integrated health system.

Under Phase III, a physician owner, employee or independent contractor of a "physician organization" (a new term in these regulations) is deemed to "stand in the shoes" of the physician organization itself, just as if the individual physician had contracted directly with the entity providing designated health services (DHS). As a result, unlike under the earlier regulations where financial arrangements between such a physician and a DHS entity could be tested using an indirect compensation analysis, now the physician is considered to have a direct compensation arrangement with the DHS entity and the arrangements must meet one of the direct compensation arrangements exceptions, which generally are more stringent than those used to analyze indirect compensation.

> **Until a final rule is issued, many arrangements currently in place or under contemplation must be brought into compliance, and hospitals will need to closely monitor these regulatory developments and rethink many of their strategies for employing and compensating associated physicians.**

The Centers for Medicare & Medicaid Services (CMS) announced a delay in the effective date for arrangements between academic medical centers or tax-exempt integrated delivery systems and their affiliated physician practices. The delay, though, is narrow and, for example, does not apply to single-hospital systems that use non-exempt affiliates to employ physicians or for-profit healthcare systems even where the hospital owns or controls the physician organization. CMS will announce a proposed rule in the next few months that will reconsider this rule in a more comprehensive manner.

Preventing Unpleasant Anti-kickback Surprises

"Fraud and abuse enforcement will be as much on the front burner in

2008 as it's ever been, especially for medical device makers and suppliers of diagnostic services. This year, fraud and abuse enforcement will also continue focusing on pharmaceutical manufacturers and the providers of services that rely on their products," says Hope Foster.

As nearly everyone in the health industry knows, the Anti-kickback and the Stark self-referral prohibitions were designed to prevent fraud and abuse in federal healthcare programs.

> **Given the consequences of violating these laws, Tom Crane notes that financial arrangements between physicians and medical device manufacturers must be driven by a thoughtful business plan and solid rationale that will bear prosecutorial scrutiny.**

Crane adds that recent "settlements in New Jersey—where manufacturers allowed federal monitoring of their operations—represent a huge sea change. Deferred prosecution agreements are turning out to be a new enforcement tool that's on the up-tick." Deferred prosecution agreements involve the imposition of a term of probation on the violator, in advance of a conviction, and the violator agrees to federal monitoring of its operations at the violator's expense. A well-devised formal business plan between physicians and manufacturers can help achieve compliance with the Anti-kickback Statute and Stark Law and avoid the threat of government enforcement action.

To facilitate compliance, Hope Foster suggests applying a very basic analysis when making business decisions. "I ask clients to begin the analysis by asking themselves three questions: First, how would you feel if this arrangement were reported on the front page of your local newspaper? Second, what does your gut tell you about it? And third, how would you feel if you had to pay for these services yourself?"

In 2007 the government pursued vigorous enforcement efforts against healthcare entities that allegedly violated the Anti-kickback and the Stark self-referral prohibition, and, without question, such efforts will persist and likely will intensify in 2008.

OIG Advisory Opinion May Leave "No Way Out" on Surgery Center Sales

In a recent advisory opinion, the Office of the Inspector General for the Department of Health and Human Services (OIG) concluded that the sale of a portion of the interests held by physician investors in an ambulatory surgery center (ASC) joint venture to a not-for-profit hospital could generate prohibited remuneration under the Anti-kickback Statute. Under the advisory opinion, these investors cannot even count on getting fair market value out of their investments—a development that has resulted

in many dissatisfied investors.

> **"This new vagary presented by the opinion, coupled with reimbursement uncertainty, technical developments, economic fluctuations, changing consumer demand and regulatory changes, make investing in an ASC joint venture anything but a sure thing for physicians," says Deborah Daccord.**

"By basing its conclusion in part on the fact that the fair market value of the interests at the time of sale would be greater than their value at the surgery center's inception, the OIG turned a fundamental premise of business transactions on its head, leaving physician investors with substantially limited options for exiting a joint venture of this type," Daccord explains.

"One possible result is an increased unwillingness of physicians to invest in joint venture ASCs, and other types of joint ventures, which could have a profound impact on patient access to new or improved services in underserved areas," she cautions. The opinion, which is only binding on the party that sought advice from the OIG, suggests that paying fair market value may no longer be sufficient to meet the Anti-kickback Statute's safe harbor in cases where the value of a joint venture interest has appreciated considerably since the time of the initial investment.

The opinion may also have significant implications for hospital-physician relationships by encouraging physicians to set up ASCs independent of the hospitals at which they have been performing surgeries. The joint venture model emerged in part because of the interest of hospitals in preserving at least some of the surgical business that otherwise might be spun off by their own physicians. As with the "stand in the shoes" provisions of Stark Phase III described above, this development initiated by the OIG will serve to complicate fostering mutually beneficial hospital-physician relationships.

What You Can Do

- **Take a good look at the Anti-kickback Statute risks** inherent in physician joint ventures, especially hospital-physician joint ventures.
- **Include carefully structured liquidity terms**, like buyout provisions, fair market value appraisal mechanisms, and affirmative representations that the transaction is not intended to generate or reward referrals.
- **Make sure the time is right.** Consider your personal investment timeline when choosing whether to invest in a joint venture—and when.

Medical Tourism Blossoms, Quality

Concerns Grow

Medical or healthcare tourism is a growing phenomenon as Americans travel abroad for affordable healthcare. With a market now estimated at $20 billion annually and numbers expected to double by 2010, American hospitals are rethinking their role.

The appeal of travel abroad for medical procedures rests, first and foremost, on the availability of less expensive healthcare elsewhere than in the United States. The economics of medical tourism," plus a plethora of amenities associated with the stay, initially made "medical tourism" attractive to patients with deep pockets. Americans went abroad principally for cosmetic surgery, a service generally not covered by insurance in the United States. Now, however, this area is receiving serious consideration by many employers for their employees and health plans for their enrollees. Services being sought are expanding to include many more complex procedures. Moreover, foreign jurisdictions are vying for the medical tourist dollar, including India, Thailand, Mexico, Costa Rica, Singapore and many Middle Eastern countries such as the United Arab Emirates, Bahrain, and Qatar.

While reduced costs are clearly a draw for patients and insurers, concerns over quality of care understandably have surfaced.

> **"We don't quite know how rigorous the standards of care are abroad," notes Steve Weiner. "Many jurisdictions haven't yet focused on quality in the way that we have here. For some, it will call for inculcating quality processes into their culture—and that may take time."**

What kind of quality care may an American "tourist" expect to find abroad? Accreditation is one measure of quality. In recent years, more than 100 hospitals and treatment centers abroad have become accredited by the Joint Commission International, an affiliate of the United States' Joint Commission. Other accrediting bodies exist in the United Kingdom, New Zealand and Australia.

Quality concerns remain, however. First, a U.S.-based accreditation agency may have difficulty applying the same standards and processes elsewhere that it uses for American healthcare facilities. Further, accreditation generally relates to institutions and not to professional practitioners such as physicians. To seek some assurance regarding quality, one must look either to the credentialing standards of the hospitals themselves or to the licensing requirements used by the foreign jurisdiction.

A related development, then, has been the expansion to foreign jurisdictions of U.S.-based healthcare providers that enjoy reputations for high quality, sometimes in conjunction with local providers and sometimes on their own. The Mayo Clinic, Joslin Diabetes Center, Weill Medical College of Cornell University, and Partners HealthCare (including Massachusetts General Hospital and the Brigham and Women's Hospital)

all are developing dynamic relationships with hospitals of international repute around the world.

What about a patient experiencing malpractice abroad? “That’s still the Wild West from the legal point of view,” says Steve Weiner. For example, in the United Arab Emirates no tort procedures currently exist, and malpractice is considered a criminal act, punishable by imprisonment. Nor does it seem to be the case, yet, that American insurers provide malpractice insurance for patients receiving care abroad, or for companies promoting “medical tourism,” who might be sued by a patient.

Key Concerns

For U.S.-based providers considering “setting up” abroad:

- Address the **legal and practical considerations in structuring affiliations** with overseas healthcare providers.
- Determine how most effectively to **maintain the standards of quality** abroad that you have at home. Do not let international activities adversely affect your brand.
- Understand the **legal environment** in which care will be provided abroad.
- Be aware of **who will pay** for the care you provide.
- Know the **malpractice jurisprudence system** in the jurisdiction.
- Consider what arrangements you will make for patients returning from care abroad in order to **maintain continuity of care**.

For U.S. patients considering seeking care abroad:

- In the absence of consistent regulatory oversight, **undertake your own due diligence** before opting to receive treatment at foreign medical institutions.
- **Learn who is liable if something goes wrong** with your surgery. In nearly all cases, liability will fall to the non-U.S.-based institution where you received care.
- **Investigate the medical training of the physicians** who will be treating you.
- Carefully **read all documents** you may be asked to sign and consult an attorney if you have any questions about what the documents mean.
- **Visit the hospital’s web site to learn more about its stated quality standards** and ascertain whether it has been accredited by any international accrediting body.
- **Ask your stateside physician** all the questions you have before committing to any procedures and attendant costs.
- **To assure continuity of care when you return, establish arrangements in advance** between your U.S. physician and the

physicians who will provide care abroad.

New York Shrinks Hospital Capacity: Will Only the Strong Survive?

New York has addressed head-on a serious concern about the structure of the state's existing healthcare system—excess hospital capacity. The Commission on Healthcare for the 21st Century (known as the Berger Commission, after its Chair, investment banker Stephen Berger) was created by former Governor Pataki and the state legislature to ensure that the regional and local supply of hospitals and nursing homes in New York State can meet community needs for high quality, affordable and accessible care in a manner that creates meaningful efficiencies in delivery and financing, and that therefore promotes longer-term stability. The Berger Commission final report was issued in December 2006 and recommended the closure of nine hospitals and the reconfiguration of 48 other hospitals across New York State. The likelihood of mergers and consolidations among healthcare institutions is certainly on the minds of hospital governing bodies and senior management in New York, where Mintz Levin has an active transactional and regulatory health law practice.

> **Andrew B. Roth, who heads up Mintz Levin's Health Law Practice in New York, cautions: "Across the state of New York, small hospitals that serve special needs should probably fare well, but increasingly, many community hospitals may need to consider becoming affiliated with healthcare systems or larger entities if they expect to survive."**

As goes New York, so too may go other parts of the country. The experience gained in fostering mergers, consolidations, reorganizations, and closures in New York is, to a large extent, transferable to other states as well.

How to Benefit from the Healthcare IT Explosion While Protecting Your Interests

Hospitals and physician practices are increasingly relying on electronic records systems and electronic communication, with the encouragement of government agencies, which are implementing protective policies and uniform standards. In the Spring of 2008, the Centers for Medicare & Medicaid Services (CMS) will begin inviting physicians to participate in a demonstration project offering financial rewards to physician practices that adopt certified electronic health records systems meeting specific clinical quality measures. CMS also recently elicited comments on a proposed rule that will set final uniform standards for e-prescribing in the Medicare Part D program.

Hospitals and physicians must not only understand the government's role in the IT revolution, but also carefully select products and partnerships with vendors to protect their own interests. Julie Korostoff, who regularly represents clients in the procurement of IT systems and related services, relayed a few of the concerns that hospitals and physicians share:

- How can you know whether you are making the best purchase decision?
- How can you vet the product?
- How can you assure you are getting the best terms?
- How can you ensure adequate training for your staff now and into the future?
- How do you know if the vendor has the "bandwidth" to meet your service needs?

According to Korostoff, users of complex IT systems in other industries such as financial services are light years ahead in this area. "They are demanding—and getting—contract protections that hospitals also should seek, such as service level agreements, specific time commitments to responding to helpline requests, penalties for nonperformance, and much more."

Movement on State Healthcare Reform Spreading Like Molasses

Massachusetts became a pioneer in comprehensive healthcare reform last year, but most other states appear reluctant to take on the issue in a significant way. Two concerns seem to be impeding the further development of improved access to services through reform.

A core part of the Massachusetts initiative is the so-called "individual mandate," which requires all residents to obtain insurance coverage. While many consider this requirement to be key to achieving coverage for all residents, it raises significant political, ideological and economic problems.

Steve Weiner, who participated in the reform efforts in Massachusetts on behalf of provider clients, notes: "Two caveats are essential to bear in mind to ensure the success of any legislation containing such a mandate. First is assuring access to affordable healthcare coverage, which means addressing many thorny issues, such as mechanisms to provide insurance with pretax dollars, benefit design, and cost-share responsibilities. The second is providing exemptions for people who truly cannot obtain such affordable coverage, which means establishing financial eligibility criteria

that helps the true hardship cases without undermining the intent of the overall mandate. Not easy tasks."

Another core ingredient is the availability of affordable, publicly subsidized coverage. Massachusetts' implementation of this aspect of reform is closely tied to a waiver from the federal government, and much of 2008, Weiner notes, will be spent renegotiating the waiver that was used to implement the reform initially. At the same time the amount of Commonwealth dollars going into the subsidies is increasing rapidly, so that the overall financing of the program will need to be reexamined in conjunction with the waiver negotiations.

For more Information on the Massachusetts reform, see **Massachusetts Enacts Landmark Health Care Reform Bill: An Overview of H. 4850, An Act Providing Access to Affordable, Quality, Accountable Health Care** (http://www.mintz.com/newsletter/2006/Health-Alert-Landmark-Reform-Bill-4-13-06/index.htm)

As an example of how difficult it is to "migrate" such reforms elsewhere, notwithstanding agreement by Governor Arnold Schwarzenegger and the California State Assembly, a Senate committee rejected a healthcare reform bill because it was unaffordable in light of the state's current fiscal crisis.

Rules Related to Purchased Diagnostic Tests Continue to Evolve

In 2007, the Centers for Medicare & Medicaid Services (CMS) made significant changes to the rules regarding reimbursement for purchased diagnostic tests. Although CMS originally announced a January 1, 2008, effective date, the agency made an eleventh-hour decision to delay implementation with respect to certain services while it takes a closer look at how the rules may apply in practice.

Under the final regulations, application of the anti-markup provisions generally depends on who orders the test and where the test is performed, and these limitations apply to both the technical component (TC) and the professional component (PC) of diagnostic tests. Specifically, CMS has imposed an anti-markup prohibition on the TC as well as the PC of diagnostic tests that are ordered by the "billing physician or other supplier" (or by a party related by common ownership or control to the supplier), if purchased from an outside supplier or if performed at a site other than the "office of the billing physician or other supplier." The term "outside supplier" essentially covers any individual or entity who is not an employee (whether full-time or part-time) or an independent contractor providing services pursuant to a valid reassignment.

The final rule leaves a number of terms open to interpretation. For instance, it does not specifically define "net charge" but does state that it must be determined "without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier." The term "office of the billing physician or other supplier" is defined as "medical office space where the physician or other supplier regularly furnishes patient care.

With respect to a…physician organization…, the 'office of the billing physician or other supplier' is space in which the physician organization provides substantially the full range of patient care services that the physician organization provides generally." CMS stated only that the term has its "common meaning" but declined to issue further guidance in the final rule.

The recently announced delay in application of the new rules applies to all services, except anatomic pathology services provided in space that meets the centralized building test under the Stark rules but that does not qualify as a same building under those same rules. This decision stems primarily from CMS's desire to address the proliferation of "pod lab" arrangements. Despite this partial delay, physicians and other suppliers should be aware that the long-standing prohibition on marking up the TC of diagnostic tests continues to apply to *all* types of services.

CMS has announced that it will issue guidance, engage in additional rulemaking, or both, in 2008. In particular, CMS has made clear that it will clarify the meaning of "office of the billing physician or supplier"—a term about which many physician group practices have raised questions. Providers and suppliers with an interest at stake should monitor this situation carefully and make their views known to CMS.