

HEALTH LAW ALERT

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RECENT STARK LAW, FALSE CLAIMS ACT CASES HIGHLIGHT IMPORTANCE OF KEEPING CONTRACTS CURRENT; NEW FRAUD PROVISIONS IN HEALTH REFORM UP THE ANTE ON COMPLIANCE

BY JESSE BERG AND TIM JOHNSON

The Stark Law contains a number of exceptions that protect common business arrangements, such as leases and services agreements. These exceptions require that a fully executed contract be in place before the arrangement commences. However, depending on a provider's size and the urgency for a new relationship to begin, it can sometimes be difficult to ensure that a written contract is signed ahead of time. Two recent cases highlight the importance of ensuring contracts are in place with referral sources in advance.

Real Estate Director Blows Whistle on Hospital's Failure to have Leases

Rush University Medical Center (RUMC) agreed to pay \$1.5 million to resolve a False Claims case premised on alleged violations of the Stark Law. According to the whistleblower, the Chicago hospital violated the Stark Law because it did not have leases for office space in place with physician groups. By providing office space for free, the Stark Law was violated with every referral from these physicians and every claim billed by RUMC to Medicare resulting from those referrals.

Several things stand out. First, the whistleblower had been in charge of RUMC's real estate arrangements and the allegations she raised were about the failure of those very arrangements to comply with the Stark Law. While the facts are murky, the notion that a whistleblower could base their False Claims case on a regulatory violation that would appear to have been within that individual's area of responsibility is troubling.

Second, RUMC had discovered the lack of leases before learning of any governmental investigation. It set about to fix the problem right away, and quickly got leases signed with the physicians involved. However, RUMC did not self-disclose the problem to the regulators. In spite of already having remedied its Stark Law problem, RUMC was nonetheless forced to pay a significant amount to the federal government.

Problems with Physician Contracts Lead to Stark Settlement

An Atlanta hospital recently entered into a settlement to resolve Stark Law liability in 22 relationships with referring physicians. The hospital uncovered a variety of arrangements where it made payments to physicians despite the absence of written contracts. The arrangements included payments for medical director services, chairing hospital departments and a contract for transplant services where the compensation paid by the hospital was different than the amount specified in the contract. The hospital self-disclosed these violations to regulators.

Many of the arrangements were out of compliance with Stark Law exceptions for only brief periods. For example, the hospital received medical director services without an executed contract for only an eight-day period in 2005. Likewise, it made payments to physicians who served on the hospital's board for just three months without having contracts in place. In spite of these short periods of noncompliance, the hospital was forced to make a settlement payment to resolve its Stark Law problems. This demonstrates just how important it is to ensure written agreements that accurately reflect the relationships with referring physicians are in place at all times.

Patient Protection and Affordable Care Act Includes New Anti-fraud Measures

A common refrain throughout the health care reform debate was that coverage expansions could be paid for by tightening the noose on fraud. While this historic legislation is still being digested, the significance of one anti-fraud provision has already emerged. The law provides that any "overpayments" must be returned to the government within 60 days of discovery. If overpayments, which are defined to mean funds from Medicare or Medicaid to which a provider is not entitled, are not returned within that time frame, they are actionable under the False Claims Act. Regulators view knowing retention of amounts paid in excess of the appropriate amount as a "reverse" false claim because a provider is keeping something to which they are not entitled.

CMS had issued proposed regulations in 2002 that would have implemented this 60-day period for refunding overpayments. The regulations were never finalized, however, due to CMS' awareness of the difficulty in meeting such a quick turn-around time. Given the severe penalties that can be imposed under the False Claims Act, providers will certainly have new motivation for ensuring that they can refund overpayments within the 60-day period.

Other changes from the PPACA include the following:

- Amendment to the Anti-Kickback Statute that provides it is not necessary to have specific intent or actual knowledge for a violation of that law to be found. This overrides case law holding that specific intent is required to violate this criminal statute.
- Physicians using the in-office ancillary services exception to comply with the Stark Law must disclose financial relationship and give patients a list of other imaging suppliers when self-referring for MRI, CT, or PET imaging.
- Medicare payments to providers can be suspended while regulators investigate "credible" allegations of fraud.
- The maximum period of time for submitting Medicare claims is reduced to 12 months.



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IT'S 2010: DO YOU KNOW WHERE YOUR MEDICAL STAFF BYLAWS ARE?

BY GREG LARSON

Recent activity by the Joint Commission has made this year an excellent time to dig out your medical staff bylaws and associated policies and procedures to ensure that they meet current standards prior to your next accreditation review. Here are three reasons to get the process rolling:

Reason One: New MS.01.01.01

It was a long time coming, but last month the Joint Commission finally adopted new medical staff standard MS.01.01.01, to be effective March 31, 2011. The new standard has a number of implications for the content of an accredited organization's medical staff bylaws, and is likely to have a substantial impact on the relationship between the medical staff executive committee and the organized medical staff.

What's New in MS.01.01.01

(1) Specified Medicare Conditions of Participation Must Be in the Bylaws. The Centers for Medicare and Medicaid Services (CMS) has been concerned that the Joint Commission's standards have not explicitly required all of CMS's medical staff-related Conditions of Participation to appear in the medical staff bylaws. In response, the new standard mandates that "every requirement" of 15 Elements of Performance (EPs) listed in the standard be set forth in the medical staff bylaws. The EPs include some areas that are commonly addressed in rules and regulations ancillary to the bylaws, such as requirements for completing and documenting medical histories and physicals, requirements relating to appointment and privileging decisions, termination and suspension, and fair hearing and appeals. For those EPs that require a process to implement, the bylaws must include at least the "basic steps" required for the implementation of the EPs. The "associated details" for implementation (as determined by the organized medical staff and approved by the governing board) may be placed in the bylaws, the rules and regulations, or other policies.

In a list of FAQs published by the Joint Commission, the Commission is optimistic that the proposed standard will not require most accredited providers to "totally revise their medical staff bylaws," at least to the extent such organizations have engaged in "robust discussion" regarding their bylaws, rules and regulations, and policies. It seems likely, however, that some revisions will be required, especially by those hospitals that have developed fair hearing policies and other procedures outside of their medical staff bylaws. Even if major revisions to the bylaws are not ultimately required, hospitals and other accredited providers will undoubtedly need to examine their current bylaws and ancillary documents, and hospital governing bodies

will often need to engage in significant discussions with the organized medical staff about what procedures or portions of procedures should migrate into the bylaws.

(2) The Role of the Medical Executive Committee.

The new standard requires that the medical executive committee (MEC) be accountable not just to the governing body of the hospital, but to the organized medical staff as well. The standard requires a hospital's MEC to notify the medical staff of any proposed adoption of or amendments to rules and regulations (policy changes do not require notice). Also, EP 8 permits the organized medical staff to introduce amendments to the medical staff bylaws, rules, and regulations directly to the governing body if, for instance, the MEC disagrees with or refuses to consider a medical staff proposal.

Recognizing that friction may develop between the MEC and medical staff, the Joint Commission also included a requirement that a medical staff create and implement a dispute resolution process to manage conflicts between the medical staff and the MEC. This new requirement is in addition to already existing Leadership Standards which require conflict resolution policies between the hospital governing board and the MEC.

Reason Two: Disruptive Behavior Policies

In July 2008, the Joint Commission published leadership standard LD.03.01.01, which took effect in 2009. That standard recognizes that certain disruptive behaviors by licensed practitioners create patient care issues, and requires accredited health care organizations to adopt a code of conduct and accompanying procedures for dealing with "disruptive" behavior by physicians and other health care professionals. Development of such policies can be a challenging process, as there are likely to be competing views regarding what kind of behaviors are truly disruptive. It is important to draft such policies with an eye to preserving a culture in which voices that constructively express concerns about quality of care continue to be heard. Frequently it is best to explicitly define both "acceptable" and "unacceptable" behavior, using supporting examples, to limit the possibility that the policy will be misapplied.

All accredited organizations are now required to have written disruptive behavior policies in place. If your organization has not yet undertaken this responsibility, it should do so now.



Reason Three: Telemedicine

Although the Joint Commission medical staff standards regarding telemedicine are not brand new, telemedicine services and methods of delivery have evolved at a pace that has outstripped revisions to some accredited providers' medical staff governance documents and procedures. Properly drafted medical staff bylaws should clearly address at least the basic steps of procedures for credentialing and privileging practitioners who provide services via telemedicine link.

MS.13.01.01 provides that practitioners who render patient services via telemedicine link are generally subject to the credentialing and privileging process of the originating site (i.e., the site where the patient is located). The standard does allow, however, the originating site to rely on the credentialing and privileging decisions made by the distant site if the distant site is a Joint Commission accredited organization and the originating site ascertains that the requested privileges do not exceed those granted at the distant site.

What Hospitals Should Do

If your organization is accredited by the Joint Commission, your medical staff will need to modify its bylaws prior to March 31, 2011, to conform to the new accreditation requirements in MS.01.01.01. Concurrent with this process, it is a good idea to also review your disruptive physician policies and telemedicine procedures if you have not done so recently. Even if your organization is not accredited by the Joint Commission, administrative and medical staff leaders may wish to discuss adopting many of the changes in MS.01.01.01 as best practices for the medical staff and its relationship to the MEC and the governing body.



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FINDING THE MEANING IN “MEANINGFUL USE” EHR STANDARDS

BY CATHERINE BITZAN

On December 31, 2009, the Centers for Medicare & Medicaid Services (CMS) issued proposed regulations that establish the initial criteria that hospitals and health care providers must meet to receive incentive payments for the “meaningful use” of certified electronic health record (EHR) technology. The Office of the National Coordinator for Health Information Technology (ONC) released corresponding regulations that describe the standards and certification criteria the EHR technology must meet for its user to receive incentive payments under the program. The proposed regulations bring highly anticipated CMS guidance regarding the implementation of the EHR incentive programs enacted under the American Recovery and Reinvestment Act (ARRA) of 2009.

What’s at Stake for Providers

The Health Information Technology for Economic and Clinical Health Act, or HITECH Act, was enacted as part of the ARRA and offers financial incentives for Medicare and Medicaid providers to become meaningful users of EHR. The HITECH Act includes separate Medicare and Medicaid EHR incentive programs. Physicians (called “eligible professionals”) must choose between participating in the Medicare or Medicaid incentive programs, but hospitals can participate in both programs simultaneously. The incentive programs have generated uncertainty and some controversy as CMS attempts to define the standards that providers must meet to receive incentive payments, such as what it means to be an eligible professional and how to demonstrate “meaningful use” of EHR.

Between \$14.1 billion and \$27.3 billion in federal incentives is at stake as providers determine whether and how to implement the meaningful use of EHR as outlined under the proposed regulations. Incentive payments are scheduled to begin in 2011 and gradually decrease until 2015, when financial penalties will start to kick in for providers who are not meaningful users of EHR. Under the incentive program, eligible professionals can receive up to \$44,000 over five years in the Medicare incentive program or up to \$63,750 over six years in the Medicaid incentive program. Eligible hospitals can receive a \$2 million base payment plus a set amount per discharge based on their Medicare/Medicaid share. It is anticipated that up to \$11.2 billion will be distributed to Medicare-eligible hospitals, \$5.4 billion to Medicare-eligible professionals,

\$4.1 billion to Medicaid-eligible hospitals, and \$6.6 billion to Medicaid-eligible professionals.

The Proposed Regulations Begin to Clarify “Meaningful Use”

The CMS proposed regulations reflect CMS’s perspective on the specific ways providers must utilize EHR in regard to patients and other providers to truly meet the goals of EHR and improve health care. These regulations represent the first of three stages of CMS rulemaking to define “meaningful use” as it relates to data capturing and sharing, advanced clinical processes, and improved outcomes.

The proposed rule offers some clarity regarding what will qualify as meaningful use of health records. Specifically, health care providers can demonstrate “meaningful use” by using their EHRs to improve the quality, safety, and efficiency of health care services; reduce health care disparities; engage patients and their families in their health care; improve the coordination of care; improve population and public health; and ensure the privacy and security of personal medical information.

The regulations provide a number of objectives and measures to determine whether eligible health care providers are making “meaningful use” of EHR. Some of these require a yes or no answer, whereas others will only apply if they are relevant to the patients or practice of the eligible provider. The objectives and measures include, for example, whether the eligible provider maintains an active medication list, incorporates clinical lab test results into EHR as structured data, reports ambulatory quality measures to CMS or the state, submits claims electronically to public and private payers, records and charts changes in vital signs, records demographics, provides patients with an electronic copy of their health information upon request, and has the capability to electronically exchange key clinical information among providers of care and patient-authorized entities. Some objectives are specific to the type of provider. For example, eligible professionals must send reminders to patients for preventative and follow-up care based on the patient’s preference, and must provide clinical summaries for patients for each office visit. Eligible hospitals and crucial access hospitals must provide patients with an electronic copy of their discharge instructions and procedures upon request, among other requirements.

The regulations also address the clinical quality measures that contribute to meaningful use. In 2011, eligible providers will be required to submit summary quality measure data to CMS or the state by attestation to demonstrate meaningful use. In 2012, providers must electronically submit their summary quality measure data to CMS or the states. Eligible professionals must submit clinical data on core quality measures (preventative care and screening inquiry regarding tobacco use, blood pressure management, and drugs to be avoided by the elderly), as well as a subset of clinical measures most appropriate to the professional’s specialty such as cardiology, oncology, or pediatrics. Eligible hospitals must report summary data to CMS or the states on 35 clinical quality measures. For the Medicaid incentive program, hospitals may select eight alternative quality measures to meet the reporting requirements if the 35 measures do not apply to their patient population. Hospitals only eligible for Medicaid will report directly to the states.

More Changes to Come

The meaningful use guidance in the proposed regulations has generated a mixture of support and criticism. Supporters point to the rules’ strong stance on aligning the potential of EHR technology with a means of using it that will maximize the quality, efficiency, and safety of patient care. Critics contend that the proposed rules are too stringent and would penalize many providers that are already using health information technology, often in innovative ways. It remains to be seen how CMS will amend the proposed rule based on a flurry of comments received during the public comment period which ended March 15, 2010. It is likely that the exact parameters of “meaningful use” will continue to evolve as research continues on the effectiveness of EHR technology in improving care coordination between patients and clinicians and providers begin to implement ways to demonstrate they are “meaningful users” of EHR.



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THURSDAY, JULY 15, 2010
Earle Brown Heritage Center, Brooklyn Center, MN

A full-day seminar covering a wide variety of topics and current issues in health law.

HEALTH CARE REFORM ROUNDTABLE WEDNESDAY, MAY 26, 2010

Death Panels, Tanning Beds, and AK47s: What Providers Need to Know About Health Care Reform

The new health care reform laws are the subject of intense media coverage and partisan analysis; however, much of this attention has focused on political issues and less coverage has been devoted to the substantive changes to health insurance payment, coverage, and delivery found in the new laws. With so much focus on hot-button questions, it can be challenging for providers to sort through the hyperbole and misinformation to understand the impact the reforms will have on health care practice.

Please join us as we discuss some of the changes most likely to affect providers. Topics to be addressed include:

- Medicare, Medicaid, and commercial payor reforms likely to drive health care delivery system changes
- Modifications to the Stark law, federal anti-kickback statute, and False Claims Act
- Modifications to the tax code affecting tax-exempt hospitals
- Disclosure requirements for physician financial relationships with drug and device companies
- New requirements for long-term-care providers
- Employer responsibilities under the new laws

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Thanks in advance for joining us in our efforts to provide you with more timely communication—and save some trees while we're at it!