

**SEMINOLE COUNTY MEDICAL SOCIETY**

**September 21, 2010**

**HOT LEGAL TOPICS**

**BY**

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**1. Rules Change for Physicians with In-House Imaging Equipment**

Under the recently enacted "Health Care Reform" legislation, physicians who refer Medicare and Medicaid patients to in-house imaging equipment must disclose in writing that they own the equipment. In addition, they will also have to tell their patients that the patients are free to obtain the diagnostic services elsewhere and provide at least ten (10) alternative sites within 25 miles. The concern is that self-referrals by physicians will lead to excessive tests and higher Medicare and Medicaid spending. This rule will take effect next year.

**2. Standard MS.01.01.01 to be Implemented by March 31, 2011**

Joint Commission Standard MS.01.01.01, formerly known as MS.1.20, has been adopted with an implementation date of March 31, 2011. This Standard, which is a combination of new, revised, and existing elements of performance (EPs), sets out the basic requirements for the following areas:

- a. Substantive provisions need to be included in Medical Staff Bylaws as opposed to separate Medical Staff Rules, or separate policies and procedures.
- b. There must be an established conflict management process when disputes arise between the organized medical staff (OMS) and the medical executive committee (MEC) and, if unresolved, the role of the hospital's Board (Board of Directors or Board of Trustees) in reviewing this conflict.
- c. There must be a mechanism or threshold for determining when the conflict management process referred to above is triggered.
- d. Requirements for fair hearing plans.
- e. The OMS will be able to propose changes to bylaws, rules, regulations, and policies directly to the Board, bypassing the bylaws committee and the MEC.
- f. Enables the MEC to propose and conditionally adopt “urgent amendments” to rules and regulations without prior OMS approval when the hospital is faced with an immediate legal mandate.
- g. Increases authority of OMS to approve and reduce MEC authority or to remove MEC members.

### **3. Health Care Reform has Arrived**

On Thursday, September 23, 2010, a number of changes brought on by the passing of the Patient Protection and Affordable Care Act (PPACA) will take effect. Specifically:

- a. Insurance policies written after this date will no longer have co-payments for about 100 preventive measures, including many immunization vaccines and mammograms.
- b. In addition to preventive measures, the new health insurance policies must allow for purchase of insurance coverage for dependants until the age of 26 and will remove policy limitations.
- c. The most significant change is that insurers will no longer be able to deny coverage to children with pre-existing conditions. This change has sparked fear that parents will wait until their child becomes sick before enrolling the child in a health insurance plan. However, this fear will be short lived as PPACA requires virtually everyone to have health insurance starting in 2014.

#### **4. Federal Court Rules No Link Between Autism and Vaccine**

On August 27, 2010, the United States Circuit Court of Appeals for the Federal Circuit upheld lower court findings that reject a causal connection between childhood vaccines and the onset of autism. The ruling came in Cedillo v. Secretary of Health and Human Services. The federal court specifically found that there was no legal error in the standards applied by the lower court in determining that there was no causal connection between the mercury-based preservative in the measles-mumps-rubella (MMR) vaccine and the retardation that the plaintiff began to show after she was injected. The Cedillo case was the first in a series of test cases heard by the United States Court of Federal Claims. The claims court picked these cases to test different theories of causation advanced in the roughly 5,000 pending cases alleging a link between autism and vaccines that have been filed under the National Childhood Vaccine Injury Act of 1986.

#### **5. Proposed Regulations Seek to Crack Down On Medicare and Medicaid Fraud**

The Centers for Medicare and Medicaid Services (CMS) unveiled new proposed regulations on September 20, 2010, that seek to crack down on Medicare and Medicaid fraud. The proposed rules are part of the "Health Care Reform" legislation that was passed on March 23, 2010, and will provide increased scrutiny of the amount spent on Medicare, Medicaid and the Children's Health Insurance Program (CHIP). These rules will require the suspension of payments to a provider as soon as there's been a "credible allegation" of fraud that merits further investigation. This includes tips from consumers. The proposed federal regulations will also require state Medicaid programs to stop using medical providers that have been kicked out of Medicare or another state's Medicaid or CHIP program. A rating system will also be adopted that will rate all types of medical providers by their risk of engaging in fraud and will require those at highest risk to undergo finger printing and criminal background checks. These proposed rules will be published September 23, 2010, for comment. They are expected to be finalized by the end of the year.

#### **6. Litigation Against Health Reform Continues**

Today, attorneys for the federal government will ask the United States District Court to throw out a lawsuit filed by Florida Attorney General Bill McCollum. On May 14, 2010, McCollum, joined by 19 other states filed a lawsuit alleging that the new health reform legislation violates the U.S. Constitution by requiring all citizens to obtain health care coverage or pay a tax penalty, among other issues. This hearing will be a first test for the closely watched case, and if the federal court judge rejects all or part of the federal government's motion, the case will move toward trial. This is just the first step in a case that is likely years from being resolved and ultimately could end up before the United States Supreme Court.

**7. U.S. Court In Massachusetts Dismisses Claims That Maker Of Growth Hormone Violated False Claims Act By Promoting Off-Label Uses**

The U.S. District Court for the District of Massachusetts on September 14, 2010, in *United States ex rel. Rost v. Pfizer, Inc.*, No. 03-11084-PBS (D. Mass. Sept. 14, 2010), granted summary judgment in favor of a pharmaceutical manufacturer in a whistle-blower action alleging unlawful promotion of the growth hormone Genotropin for off-label pediatric uses. The court rejected the whistle-blower's (Rost's) allegations that defendants Pfizer, Inc., and Pharmacia Corp. provided illegal kickbacks to physicians to prescribe Genotropin and ultimately caused pharmacies that filled the prescriptions to submit false claims to the Kentucky and Indiana Medicaid programs. The court found Rost could not proceed on an implied certification theory of liability as a matter of law where, as here, the pharmacies that submitted the alleged false claims were innocent of wrongdoing and the claims were not factually false.