

February 4, 2010

**FIRST ARREST EVERYBODY-- NOTES ON THE NATIONAL SUMMIT ON HEALTHCARE FRAUD**

"In some districts they don't like to arrest white collar defendants. . . . We arrest everybody. Everybody gets arrested. No one walks." That was one comment heard from enforcement agents on Thursday, January 28, 2010, as the U.S. Departments of Justice (DOJ) and Health and Human Services (HHS) brought together law enforcement, private and public sector leaders and healthcare experts for the "National Summit on Health Care Fraud," the first national gathering of this kind and an initiative of the Health Care Fraud Prevention & Enforcement Action Team (HEAT).

HHS Secretary, Kathleen Sebelius, reiterated the Obama administration's "zero tolerance" policy for fraud and alluded to a "historic" budget allocation for anti-fraud efforts that she anticipates will result in billions in savings. The summit focused on a two-pronged strategy of prosecution and prevention to help curtail the estimated \$60 billion lost in public and private sectors yearly due to healthcare fraud.

In 2009, the DOJ charged more than 800 healthcare fraud defendants and obtained more than 580 convictions. On the civil enforcement side, the DOJ recovered \$2.2 billion under False Claims Act (FCA) cases. Attorney General Eric Holder attributed much of this success to Medicare Fraud Strike Force teams, consisting of federal prosecutors, FBI agents and agents from HHS's Office of Inspector General (OIG). Strike Force teams, described as the "core" of HEAT's law enforcement mission, were introduced to Miami in 2007 and have since expanded to Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge and Tampa Bay.

The Attorney General outlined a roadmap for the ongoing fight against fraud: a reinforced effort on strengthening HEAT, an expansion of Medicare Fraud Strike Forces to other geographic areas, budgetary investments to properly fight fraud, regulatory reform in order to prevent and deter fraud and the continued inclusion of the private sector in anti-fraud efforts.

Workgroups met in the afternoon in closed breakout sessions to discuss the use of technology to prevent and detect healthcare fraud; the role of states in preventing healthcare fraud; the development of effective prevention policies and methods for insurers, providers and beneficiaries; effective law enforcement strategies; and measuring healthcare fraud, assessing recoveries and determining resource needs. Summaries of the workgroup discussions will be made publicly available in a report.

Also, enforcement agents suggested that HEAT is moving toward arresting individuals more quickly in order to curtail any ongoing suspected fraud, even if the case still is being investigated. One speaker noted that "Everything moves faster. . . . The times have changed. . . . We target everybody that the data indicates is an offender. We charge them quickly . . . ." The speaker further commented that "Some [agents] can't wait for that [obtaining a complaint]. . . . They go to investigate the guy. They call the prosecutor up. They're arrested on the spot. We'll do the complaint later. All of that is legal." While the benefits of curtailing ongoing fraud as quickly as

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possible are obvious, such prosecution strategies carry a risk that innocent providers and suppliers working to comply in a heavily regulated area could arguably be cast by federal authorities as guilty until proven innocent.

Federal law enforcement officials could not be clearer that providers and suppliers should prepare for increased scrutiny and enforcement in the coming year. In the fervor to catch the wrongdoers, honest providers may find themselves swept up in the wide net that the HEAT efforts cast. Physicians, hospitals and other providers should continue efforts to meticulously document their compliance efforts, especially with regard to medical necessity.

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## NEW FRAUD DETERRENCE LEGISLATION -- REFORM DEJA VU + MORE

In what could mark the beginning of a "split and scatter" strategy by Congress to convert chunks of the sputtering health reform legislation into a series of smaller stand-alone bills, Sen. Charles Grassley (R-Iowa) introduced the 100+ page "[Strengthening Program Integrity and Accountability Act in Health Care](#)" (S. 2964) on January 28, 2010. A fraud and abuse deterrence bill "comprised of reforms with bipartisan support" from the Senate healthcare reform bill, the proposed Grassley legislation also includes several new provisions affecting the federal False Claims Act. Key highlights of the proposed legislation follow below.

### Enhanced Provider Screening and Enrollment

Authorizes the Secretary of HHS to (1) standardize the provider enrollment process among the Medicare, Medicaid and CHIP programs; (2) impose additional screening measures, such as criminal background checks, fingerprinting, unannounced site visits, database checks and periods of enhanced oversight; (3) impose a temporary moratorium on enrolling new providers; and (4) set new enrollment and/or re-enrollment disclosure requirements. The new legislation also requires Medicare, Medicaid and CHIP providers to establish compliance programs.

### Reporting & Return of Overpayments

Requires overpayments to be reported and returned no later than 60 days after the date on which "the overpayment was identified or the date any corresponding cost report is due." Overpayments reported after this date may be subject to liability under the False Claims Act.

### Enhanced Civil Monetary Penalties (CMPs)

Subjects persons who make false statements on enrollment applications for participation in federal healthcare programs or who fail to return an overpayment to a minimum CMP of \$50,000 and an assessment of up to three times the amount claimed; mandates that persons who knowingly make, use, or cause to be made or used, any false statement material to a fraudulent claim be subject to CMPs of \$50,000 per violation; subjects persons to CMPs of \$15,000 per day for failing to grant timely access to the OIG during an audit, investigation or evaluation; increases the number of violations subject to sanctions and CMPs for Medicare Part C (Medicare Advantage) and D plans.

### Required Payment Suspension/Extended Payment Periods

Requires the Secretary of HHS to suspend payments to a provider or supplier pending a fraud investigation and authorizes the Secretary to extend the time that Medicare payments must be made to providers if there is a determination of the likelihood of fraud, waste and abuse.

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### Additional Funding for Program Integrity/Statistical Reporting

Increases funding for healthcare fraud activities under the Health Care Fraud and Abuse Control Account (HCFAC) by \$10 million each year from 2011 through 2020; requires both Medicare and Medicaid Integrity Program contractors to provide the Secretary of HHS with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals and the return on investment for such activities.

### Self-Referral Disclosure Protocol (SRDP)

Requires the Secretary of HHS, in cooperation with the OIG, to establish an SRDP "to enable healthcare providers and suppliers to disclose actual or potential violations of the physician self-referral law."

### Expanded Recovery Audit Contractor (RAC) Program

Expands the RAC program to Medicaid and Medicare Parts C and D by December 2010.

### False Claims Act Provisions

New provisions in the proposed legislation related to the federal FCA include a two-year statute of limitations for the filing of claims alleging retaliation under 31 U.S.C. § 3730(h) and a provision to prevent whistleblowers from being dismissed in instances where a corresponding state FCA case not joined by the federal government is filed or in cases where the federal government opposes the dismissal. The new legislation also would amend the "original source" exception to the public disclosure bar allowing whistleblowers to go forward with an FCA case that includes allegations publicly disclosed only if the whistleblower reported the fraud to the government before the disclosure or if the whistleblower provides information to the government that "materially adds" to the publicly disclosed information.

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## THE PRESIDENT'S FY 2011 BUDGET REQUEST -- A HEALTH REFORM WORKAROUND?

Characterizing healthcare costs as "the single biggest threat to our Nation's fiscal future," President Obama outlined his \$3.8 trillion FY 2011 budget request to Congress this week. From a fiscal perspective, the budget document assumes enactment of specific provisions from the now-stalled health reform legislation, saving an anticipated \$150 billion over ten years. With regard to the immediate concerns of state Medicaid budgetary shortfalls, the President's budget request extends the temporary Federal Medical Assistance Percentage (FMAP) increase provided under the American Recovery and Reinvestment Act of 2009 (ARRA) for six months, resulting in an additional \$25.5 billion to the states. It also seeks to extend COBRA premium assistance for 12 months and provides for a 10-year fix to the statutorily mandated payment reduction under the Medicare physician fee schedule.

With health reform sputtering in Congress, physician advocacy groups quickly realized that doctors soon would be subject to the 21 percent payment cut looming under the Medicare sustainable growth rate (SGR) formula. As an initial step for addressing their concerns, congressional leaders last week agreed to except out legislative efforts aimed at averting cuts to the physician fee schedule for five years from the "pay-as-you-go" rules for new spending. As discussed in the [January 21 issue of the Health Law Update](#), separate legislation to prevent the payment reduction from becoming effective still must be passed by Congress prior to March 1, 2010. Watch for physician groups to continue to push for immediate reformation of the SGR budgetary mandate with another freeze following the expiration of the February deadline.

While the administration's budget proposal for FY 2011 does not appear to contemplate additional cuts in Medicare, the President has asked Congress to create "a bipartisan fiscal commission charged with identifying additional policies to put our country on a fiscally sustainable path . . . by 2015." With analysts projecting an unprecedented 17.3 percent share of the nation's gross domestic product for healthcare, expect Medicare spending cuts to remain high on the nation's policy agenda in the coming years.

With the fate of comprehensive health reform legislation still in question, the budget document shows that the administration continues to pursue delivery system and payment reforms. To that end, the budget document allocates \$268 million for comparative effectiveness research and an increase of \$110 million to the Centers for Medicare and Medicaid Services (CMS) for "modernizing the Medicare and Medicaid programs by making CMS a leader in value based purchasing."

Chief among the budget proposal's revenue enhancers is a renewed focus on healthcare fraud prevention and program integrity, described as a "top priority for the President." The budget document provides \$561 million in HCFAC discretionary funding and infuses the joint HHS-DOJ HEAT task force with an additional \$250 million for investigative and enforcement initiatives. With HCFAC funding levels at \$1.7 billion for FY 2011, it is clear that the administration intends making significant inroads on fraud prevention and program integrity during the next fiscal year.

The President's budget document includes support for public health advancements, including HIV/AIDS prevention and treatment as well as funding for genomics, translational research and biomedical research under the National Institutes of Health. Additional dollars also are allocated for maternal and child health block grants, autism and developmental disorders, cord blood stem cell bank, emergency medical services for children, children's mental health services and efforts to combat childhood obesity.

Reforms? Yes, they are coming still and likely will surface in a multitude of vehicles -- not only via the budget and "must pass" legislation, but also through regulation and by executive order. As demonstrated by the President's budget request, the healthcare industry can ill afford to take a collective breather to rest and reflect now that a comprehensive reform bill appears to be hanging in the balance. Providers, physicians, suppliers and others must remain sensitive to continuing policy and payment changes, anticipated delivery system reforms and aggressive program integrity efforts so they may respond appropriately to ensure continued viability and success.

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## SENTINEL EVENT ALERT -- PREVENTING MATERNAL DEATHS

On January 26, 2010, The Joint Commission (TJC) issued a Sentinel Event Alert concerning maternal death. Since 1996, a total of 84 cases of maternal death, defined as a death occurring within 42 days of birth or termination of pregnancy, have been reported to TJC's sentinel event database. While still rare, the rate of maternal mortality was 13.3 deaths per 100,000 live births in 2006, significantly greater than the U.S. government's Health People 2010 goal of 3.3 deaths per 100,000 live births. Rather than decreasing, there is evidence that the maternal mortality rate actually may be increasing.

In response to this surprising trend, TJC issued this Sentinel Alert both to remind hospitals of the existing standards applicable to maternal health and provide suggested actions aimed at improving hospitals' training and protocols. Beginning in 2010, TJC Standards for Hospitals require each hospital to (1) have a process for recognizing and responding as soon as a patient's condition appears to be worsening; (2) develop written criteria describing early warning signs of a change or deterioration in a patient's condition and when to seek further assistance; (3) based on the hospital's early warning criteria, have staff seek additional assistance when they have concerns about a patient's condition; and (3) inform the patient and family how to seek assistance when they have concerns about the patient's condition. In addition to these basic requirements, TJC suggests hospitals take the following steps to help prevent maternal death:

- Educate physicians and other clinicians who care for women with underlying medical conditions about the additional risks that could be imposed if pregnancy were added.
- Identify specific triggers for responding to changes in the mother's vital signs and clinical condition and develop and use protocols and drills for responding to changes.
- Educate emergency room personnel about the possibility that a woman, whatever her presenting symptoms, may be pregnant or recently may have been pregnant.

When presented with a patient identified as high-risk, TJC suggests that hospitals also:

- Refer high-risk patients to the care of experienced prenatal care providers with access to a broad range of specialized services.
- Make pneumatic compression devices available for patients undergoing cesarean section who are at high risk for pulmonary embolism.
- Evaluate patients who are at high risk for thromboembolism for low molecular weight heparin for postpartum care.

While studies disagree regarding the percentage of maternal deaths that actually may be preventable, TJC has crafted these standards and suggestions in an attempt both to reduce the maternal mortality rate and avoid serious maternal complications.

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## NEW RULES -- PARITY IN TREATING MENTAL, SUBSTANCE USE DISORDERS

In an effort sure to impact providers with regard to the delivery of mental health services to patients, the U.S. Departments of HHS, Labor and the Treasury (collectively, departments) jointly released an [interim final rule](#) on February 2, 2010, that requires group health plans to treat medical and mental health benefits equally. Developed in conjunction with the departments' review of more than 400 public comments received in response to a request for information issued April 2009, the interim final rule implements the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) (Pub. L. No. 110-343) which prohibits group health insurance plans from restricting access to care by limiting benefits and requiring higher patient costs than those that apply to general medical or surgical benefits. Specific comments being solicited by the interim final rule include "non-quantitative treatment limits, such as those that pertain to the scope and duration of covered benefits; how covered drugs are determined (formularies); coverage of step-therapies; "scope of benefits" or continuum of care." The interim final rule, which generally applies to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010, is effective April 5, 2010. Comments, which may be sent to any of the three departments, are due on or before May 3, 2010.

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## GREG ETZEL NAMED OUTSTANDING HEALTHCARE LITIGATOR

[Gregory N. Etzel](#), a partner in Baker Hostetler's Houston office, was selected as an Outstanding Healthcare Litigator by *Nightingale's Healthcare News*. *Nightingale's Healthcare News* is a newsletter for professionals serving the healthcare industry, healthcare executives and other industry organizations. Each issue contains articles on the latest industry business news and reports on healthcare, transactions, firms and individuals of interest.

Mr. Etzel's 2009 accomplishments included obtaining two federal court victories in cases of first impression. In *HealthEast Woodwinds Hospital v. Sebelius*, the Minnesota federal district court rejected CMS's policy not to apply favorable "capital hold harmless" payment policy to the hospital. In *Bayside Medical Center v. Sebelius*, the D.C. district court ruled favorably for critical access hospitals "deemed rural" by statute.

Congratulations to Mr. Etzel for receiving this honor for the second year in a row.

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## EVENTS CALENDAR

### March 17-18

Cleveland partner Steven Eisenberg will speak on "Developing Best Practices for a Breach Assessment Process" at the HIPAA Compliance Congress: Data Protection and Privacy Compliance under the HITECH Act sponsored by the American Conference Institute at The Helmsley Park Lane in New York, New York.

### March 22

Cleveland partner Steven Eisenberg will speak on "Imaging Center Acquisitions and Plans for Consolidations in 2010" at Imaging 100 sponsored by The Summer Group taking place at the Chateau Elan in Atlanta, Georgia.

### April 8

Houston partner Susan Feigin Harris will speak on "Healthcare Reform, Part II; Delivery System Reform and the Market Response -- How Will It Affect Providers?" at the University of Texas Health Law Conference at the Four Seasons Hotel in Houston, Texas.

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