

# HEALTHCARE COMPLIANCE NEWSLETTER

Issue 5, Summer 2013

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*This newsletter is prepared by the Office of Compliance and is intended to provide you with current information about healthcare compliance and HIPAA privacy issues. For additional information, to view past newsletters, or to provide comments about this or any future issues of this newsletter, please contact the Office of Compliance at (213) 740-8258 or at [complian@usc.edu](mailto:complian@usc.edu).*

## Let the Sunshine In

Starting August 1, 2013, manufacturers and GPOs will begin reporting payments or 'transfers of value' made to physicians or teaching hospitals. 'Transfers of value' can refer to consulting fees, gifts, entertainment, travel/lodging, etc. that are valued at \$10 or more. The Centers for Medicare and Medicaid (CMS) will collect the data annually and publish it on its website. In 2014, physicians and teaching hospitals will be able to register with CMS to view data that has been reported prior to CMS posting the data publicly. There will be a limited period of time in which to review and dispute the data before it is publicly reported. We encourage providers to enroll in the e-mail updates noted in the link to keep informed of these developments.

Read more [here](#).

## Alert: HIPAA Final Rule Compliance Effective Date September 23, 2013

As mentioned in the previous newsletter, the Department of Health and Human Services (HHS) published final regulations (the Final Rule) to implement provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act enacted by Congress in 2009 which significantly modified requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Final Rule contains many important changes for covered entities and business associates. Some of these changes include expanding the definition of business associates and applying direct liability to business associates for failing to comply with HIPAA; changing the definition of marketing and expanding the information that can be shared for development/fundraising activities; expanding the definition of a breach of health information; restricting disclosures of health information to a health plan if an individual requests to so after paying for services out of pocket and in full. As a result of the many changes, the USC Office of Compliance continues to evaluate and revise certain policies and procedures and previous guidance to be in compliance by the effective date of September 23, 2013.

For more information about the Final Rule, please visit: <http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf>

## Six People Fired from Cedars-Sinai over Patient Privacy Breaches

Five workers and a student research assistant at Cedars-Sinai Medical Center have been fired over privacy breaches involving patient medical records. Cedars-Sinai officials said in a statement that 14 patient records

were "inappropriately accessed" between June 18 and June 24. Six people were fired over the breach: four were employees of community physicians who have medical staff privileges at the hospital, one was a medical assistant employed by Cedars-Sinai, and one was an unpaid student research assistant.

For more information, please see <http://www.latimes.com/news/local/la-me-hospital-security-breach-20130713,0,7850635.story>

## **OIG Pushes for Monthly Blacklist Cross-check**

Amid looming shortages in healthcare workers, one branch of the federal government is ramping up aggressive efforts to keep some of them far away from patients.

HHS' Office of the Inspector General adds about 300 new names every month to its List of Excluded Individuals and Entities (LEIE) that are banned from working for Medicare and Medicaid. The growth of the healthcare blacklist is expected to accelerate in tandem with the widening crackdown on healthcare crooks, fraudsters and clinicians who don't repay government-backed student loans.

More than 5,500 doctors and nurses joined the list after convictions for patient abuse or neglect, while another 14,200 people were excluded after their local licensing boards disbarred them for unstated reasons. Most exclusions last five years, but some are longer and a few are lifetime bans.

After years of murky standards, HHS' inspector general announced this past May that every healthcare employer in the nation that cares for Medicare patients should perform monthly checks of their entire payroll rosters-including temporary nurses, doctors and subcontractors-to see if they're employing people they shouldn't.

Read more [here](#).

## **Adventist Health Pays United States and State of California \$14.1 Million to Resolve False Claims Act Allegations**

Adventist Health System/West, dba Adventist Health and headquartered in Roseville, in the Eastern District of California, and its affiliated hospital White Memorial Medical Center have agreed to pay the United States and the state of California \$14.1 million to settle claims that they violated the False Claims Act, the Justice Department announced on May 3, 2013. Adventist Health operates 19 hospitals and over 150 clinics in California, Hawaii, Oregon, and Washington. White Memorial Medical Center is a teaching hospital located in Los Angeles.

The settlement announced resolves allegations that Adventist Health improperly compensated physicians who referred patients to the White Memorial facility by transferring assets, including medical and non-medical supplies and inventory, at less than fair market value. Additionally, Defendant White Memorial paid referring physicians compensation that the United States contended was above fair market value to provide teaching services at its family practice residency program. The United States alleged that these payments violated the Anti-Kickback Act and Stark Statute, and by extension, the False Claims Act. Approximately \$11.5 million of the settlement will be paid to the U.S. Government, most of which

will benefit the Medicare Trust Fund. The remaining \$2.6 million will be paid to California's Department of Health Care Services.

As part of the settlement, White Memorial has entered into a comprehensive five-year Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services to ensure its continued compliance with federal health care benefit program requirements.

Read the full press release here: <http://www.justice.gov/opa/pr/2013/May/13-civ-507.html>

## **OIG Issues Special Fraud Alert on Physician-Owned Distributorships (PODs)**

On March 26, 2013, the Office of the Inspector General ("OIG") of the Department of Health and Human Services issued its first Special Fraud Alert in three years. The new Alert focuses on physician-owned distributorships ("PODs"). The Special Fraud Alert is of most direct importance to medical device companies and distributors that have sometimes found themselves at loggerheads with PODs, and to hospitals and ambulatory surgical centers with active or prospective PODs.

OIG's analysis is sharp, describing PODs as "inherently suspect under the anti-kickback statute," and as presenting "four major concerns typically associated with kickbacks - corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition." OIG listed "suspect characteristics," including whether-

- higher volume physicians are offered larger investment opportunities;
- physician owners receive higher returns than non-physician owners;
- physician owners are pressured to use or refer the devices sold by the POD;
- a non-practicing physician must tender his/her shares for repurchase;
- the POD does not maintain continuous oversight of all distribution functions;
- the POD predominantly serves the area in which its physician owners practice;
- physician owners conceal their ownership interest in the POD from others;
- there are relatively few physician owners;
- physicians' practice patterns change shortly after becoming owners;
- or
- the primary users of a POD's products are its owners.

While focusing on PODs, the Special Fraud Alert makes some statements that have broader implications in the industry. First, the criteria that OIG listed, together with OIG's other existing guidance in the area, should be part of the regulatory analyses of joint ventures with referral sources generally. Second, OIG began its analysis by reaffirming that "longstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit...could constitute illegal remuneration under the anti-kickback statute." Finally, OIG noted that a physician's disclosure of his or her interest in a POD is insufficient to ameliorate the risks that OIG believes PODs present. Coming on the heels of CMS's final rule implementing the Federal Sunshine Law, this carries the flavor of a warning that disclosure of financial relationships does not suffice to eliminate risks that they otherwise present, and certainly will not foreclose further inquiry.

Read the full Ropes & Gray Alert here:

[www.ropesgray.com/files/.../20130327\\_Health\\_Care\\_Alert.pdf](http://www.ropesgray.com/files/.../20130327_Health_Care_Alert.pdf)

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