

HEALTHCARE COMPLIANCE NEWSLETTER

Issue 11, Spring 2016

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This newsletter is prepared by the Office of Compliance and is intended to provide you with current information

Cloning of Progress Notes, Upcoding Lead to Fraud Settlement; Doctors Pay \$422,000

The cloning of electronic medical records has led to a fraud settlement, possibly for the first time. Somerset Cardiology Group, P.C., in Somerville, N.J., agreed to pay \$422,741 in a civil money penalty (CMP) settlement stemming from allegations it submitted false or fraudulent claims.

Cloning refers to copying and pasting notes from one patient encounter to another without updating the information. Documentation is considered cloned if every entry in the record is worded the exact same way or it's very similar to previous entries. When entries are copied and pasted without being edited, this doesn't meet medical necessity requirements for Medicare coverage because documentation isn't specific enough to the patient and his or her experience. EHR shortcuts could set in motion claim denials and potential fraud allegations.

You can find USC's policy on EMR Key Documentation Standards [here](#).

Olympus Has Fallen: False Claims Act Whistleblower Lawsuit Prompts Medical Device Titan to Strike a Record \$623M Settlement

In yet another historic achievement under the False Claims Act ("FCA"), medical device titan Olympus Corporation of the Americas ("Olympus") announced today it has agreed to pay \$623 million to resolve a civil whistleblower suit and companion criminal charges that the company gained market share dominance for its medical products through systemic violations of the US Anti-Kickback Statute ("AKS"). The settlement is the largest total amount paid in U.S. history for violations of the AKS and the largest amount ever paid by medical device company.

The New Jersey U.S. Attorney's Office, in collaboration with the Department of Justice, led the federal investigation that corroborated the whistleblower's allegations of an elaborate, international kickback scheme, which includes:

- Providing key accounts with "permanent loans" of Olympus medical equipment virtually whenever requested by Olympus sales and marketing personnel;
- Funneling cash payments of as much as \$100,000 annually to reward "VIP" and "KOL" physicians for ostensible "consulting services" at the discretion of Olympus sales and marketing representatives;
- Annual cash payments of hundreds of thousands of dollars masquerading as "grants" to fund educational or research programs made at the discretion of a grant committee comprised solely of

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 compliance@usc.edu.

The USC Help & Hotline is a number that all faculty, staff, and students can use to report suspected violations of an applicable law, regulation, or university policy confidentially and without fear of retribution. The Help & Hotline can also be used to ask questions about applicable laws, regulations, and university policies that may impact your job duties.

*The USC Help & Hotline is staffed 24 hours a day, 365 days a year: (213) 740-2500 or file on the [web](#) and enter **UOSC** as the access code.*

Olympus sales and marketing personnel, based on sales potential; and

- Funding luxury, all-expense paid vacations to Japan and other exotic international destinations for "VIP physicians," and sometimes their spouses, in exchange for purchases and promotion of Olympus medical products.

The False Claims Act is widely heralded as the Government's most effective weapon to combat corporate schemes that generate profit from bilking Government programs funded with hard-earned taxpayer dollars. In addition to payment of the \$623 million settlement, Olympus has admitted facts attested to in connection with a deferred prosecution agreement, and the company agreed to be bound by a Corporate Integrity Agreement.

The University's policy regarding Relationships with Industry requires that a healthcare professional requesting the purchase of items must disclose any relationships with the manufacturer for consideration in the purchase assessment. You can find the policy here: <http://policy.usc.edu/industry-relationships/>

Read the full article [here](#). And here is an article about the Olympus settlement on [NPR's website](#).

Read the [Whistleblower Complaint](#).

Read the [Settlement Agreement](#).

More Than 450 Hospitals Pay Over \$250 Million in Cardiac-Device Investigation

More than 450 hospitals have settled with the government for more than \$250 million as part of a years long, nationwide investigation into the suspected overuse of implantable cardiac devices, the U.S. Justice Department announced in October 2015.

The Justice Department said it is continuing to investigate more hospitals and health systems. Some say the settlement is the largest ever under the False Claims Act based on the number of hospitals involved.

The investigation has raised awareness among hospitals across the country about Medicare's national coverage determination for implantable defibrillators. That investigation is credited with lowering the number of the devices implanted in recent years. Physicians billed Medicare for the devices for 51,052 beneficiaries in 2013 compared with 70,969 beneficiaries in 2008, according to one of the whistle-blowers.

Read the full article here:

<http://www.modernhealthcare.com/article/20151030/NEWS/151039998>

DOJ Seeks to Revamp and Re-Energize Its Prosecution of Individuals: Key Takeaways

Deputy Attorney General Sally Yates, in a memorandum entitled "Individual Accountability for Corporate Wrongdoing," wrote that the prosecution of individual corporate employees deters future illegal activity, incentivizes reforms to corporate behavior, ensures that the proper parties are held responsible for criminal actions and promotes public confidence in the justice system.

The Yates Memo indicates that the government is interested in bringing more criminal prosecutions as a result of civil investigations, and vice versa. This could dramatically change the landscape of certain types of investigations and litigation, especially involving the False Claims Act.

The memo also makes clear that the DOJ will no longer consider executives and individual actors as merely secondary targets. These new policies are also likely to dramatically alter the way corporate investigations are handled by the DOJ and defense attorneys. Typically, when the DOJ begins an investigation into a corporation, attorneys conduct internal investigations which focus on the conduct of the corporation and the adequacy of its internal controls. Now companies must focus on identifying responsible individuals and gathering information to relay to the DOJ about those individuals. Defense attorneys, like their counterparts in the government, need to be thinking beyond mere corporate liability from the outset of the case. And, as companies gather information to turn over regarding their executives and employees to the DOJ, they need to be very sensitive to potential conflicts of interest that may arise as a result of the increased focus on identifying individual targets for the government.

You can find the full article here:

<https://www.dlapiper.com/en/us/insights/publications/2015/09/doj-seeks-to-revamp/>

And the actual policy: <http://www.justice.gov/dag/file/769036/download>

CMS Cutting-Edge Technology Identifies & Prevents \$820 Million in Improper Medicare Payments in First Three Years

After three years of operations, the Centers for Medicare & Medicaid Services (CMS) reported on July 14, 2015 that the agency's advanced analytics system, called the Fraud Prevention System, identified or prevented \$820 million in inappropriate payments in the program's first three years. The Fraud Prevention System uses predictive analytics to identify troublesome billing patterns and outlier claims for action, similar to systems used by credit card companies. The Fraud Prevention System identified or prevented \$454 million in Calendar Year 2014 alone, a 10-to-1 return on investment.

The Fraud Prevention System was created in 2010 by the Small Business Jobs Act, and CMS has extensively used its tools, along with other new authorities made possible by the Affordable Care Act, to help protect Medicare Trust Funds and prevent fraudulent payments. For instance, last month, Health & Human Services (HHS) and the Department of Justice announced the largest coordinated fraud takedown in history, resulting in charges against 243 individuals, including 46 doctors, nurses, and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$712 million in false billings.

You can read the full release here:

<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-07-14.html>

OIG Releases Semiannual Report to Congress

The Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") recently released its Semiannual Report to Congress ("Report"), summarizing OIG's activities for the six-month period ending on March 31, 2015.

The Report highlights OIG's accomplishments over the first half of FY 2015, including:

- Expected recoveries of over \$1.8 billion, comprised of approximately \$544.7 million in audit receivables and \$1.26 billion in investigative receivables.
- 486 criminal actions against individuals and entities that engaged in crimes against HHS programs
- 326 civil actions, including false claims cases, unjust-enrichment lawsuits, civil monetary penalties settlements, and administrative recoveries related to provider self-disclosure matters.
- Exclusions of 1,735 individuals and entities from participation in Federal health care programs.

In addition, the Report emphasizes the efforts and accomplishments of the Health Care Fraud Prevention and Enforcement Action Team ("HEAT"), a collaborative program between HHS and the Department of Justice launched in 2009. Moreover, the Report compiles and summarizes the various individual reports OIG published over the first half of FY 2015 regarding its efforts to reduce waste or inefficiency in the Federal health care programs.

For the full story, please visit <http://www.natlawreview.com/article/oig-releases-semiannual-report-to-congress>.

And the report can be found on the OIG's website:
<https://oig.hhs.gov/reports-and-publications/semiannual/index.asp>