

HEALTHCARE COMPLIANCE NEWSLETTER

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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 compliant@usc.edu.

HITECH Omnibus Final Rule Released

On January 25, 2013, the Office for Civil Rights ("OCR") of the U.S. Department of Health and Human Services ("HHS") published in the Federal Register a final omnibus rule ("Final Rule") that revises certain rules promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). These revised rules were issued pursuant to changes enacted by Congress in the Health Information Technology for Economic and Clinical Health ("HITECH") Act and the Genetic Information Nondiscrimination ("GINA") Act of 2008.

Effective March 23, 2013, the Final Rule revises and finalizes an interim notice of proposed rulemaking ("Interim Rule") that OCR had published in 2009, although in many cases the date by which "covered entities" regulated by HIPAA ("Covered Entities") and their "business associates," as defined by the Final Rule ("Business Associates"), must comply with the new or modified rules will be September 23, 2013 or later. In some cases, the Final Rule grandfathers arrangements entered into under the Interim Rule. Prior to the Interim Rule and the Final Rule, the HIPAA Privacy and Security Rules focused primarily on health care providers, health plans, and other entities that process health insurance claims. The Final Rule now expands many of the HIPAA Privacy and Security Rule requirements to directly regulate Business Associates that receive protected health information, including their subcontractors.

Furthermore, penalties have been increased for noncompliance. The Final Rule also expands the duty to give notice to individuals when there has been a breach of unsecured protected health information. For more information please visit: <http://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf>

Two UC Davis Neurosurgeons Accused of Experimental Surgery are Banned from Human Research

Dr. J. Paul Muizelaar, a prominent UC Davis neurosurgeon, was ordered to "immediately cease and desist" from any research involving human subjects after he and a fellow researcher were accused of experimenting on brain cancer patients without university permission. In October 2011, the university's vice chancellor for research admitted to the U.S. Food and Drug Administration that the surgeons' actions amounted to "serious and continuing noncompliance" with federal regulations. The surgeons obtained the consent of three terminally ill patients with malignant brain tumors to introduce bacteria into open head wounds under the theory that postoperative infections might prolong their lives. Two of the patients developed sepsis and died.

Read more here: <http://www.sacbee.com/2012/12/23/5072625>

Steven Cohen Implicated in Alleged Insider-Trading Scheme

U.S. officials for the first time Tuesday implicated Steven A. Cohen, the founder of SAC Capital Advisors, in an alleged insider-trading scheme they said was the most lucrative ever to be charged. Mr. Cohen wasn't charged or mentioned by name. He is referred to as "Portfolio Manager A" in an alleged \$276 million insider-trading scheme in a civil complaint filed by the Securities and Exchange Commission, according to people familiar with the matter.

In the criminal complaint unsealed Tuesday, federal prosecutors alleged that Mathew Martoma, a portfolio manager at SAC Capital affiliate CR Intrinsic Investors, received confidential information over an 18-month period from a neurology professor about a trial for an Alzheimer's drug being jointly developed by Elan Corp. and Wyeth, which is now part of Pfizer Inc. He allegedly purchased shares in the pharmaceutical companies and later sold their shares short when he learned negative news ahead of an announcement about the drug trial in 2008.

The neurology professor, Sidney Gilman, was chairman of the safety committee overseeing the drug trial and moonlighted as a paid consultant for a New York expert-network firm, which links industry experts with investors for a fee, according to a civil complaint filed by the SEC.

Dr. Gilman, who has only been charged in the SEC complaint, was paid nearly \$108,000 for meeting with persons from CR Intrinsic and an unnamed investment firm, including 42 meetings with Mr. Martoma, the SEC said.

Read the full article here: <http://online.wsj.com/article/SB10001424127887323713104578130930796204500.html>

Vast Cache of Kaiser Patient Details was Kept in Private Home

Federal and state officials are investigating whether healthcare giant Kaiser Permanente violated patient privacy in its work with an Indio couple who stored nearly 300,000 confidential hospital records for the company. For more information, please visit:

<http://articles.latimes.com/2013/jan/05/business/la-fi-kaiser-patient-privacy-20130105>

DOJ Puts Academic Medical Centers in Spotlight

On November 27, 2012, the U.S. Department of Justice announced that Baylor University Medical Center has agreed to pay nearly \$1 million to settle whistleblower claims brought under the False Claims Act, alleging that Baylor double-billed Medicare for certain procedures and billed for more expensive services when different, less expensive services should have been billed. The settlement, which DOJ hailed as an example of increased cooperation between DOJ and HHS under the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, follows a string of recent cases in which DOJ has targeted

higher education institutions under the FCA.

Read the announcement here:

<http://www.justice.gov/opa/pr/2012/November/12-civ-1413.html>

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