Industry, Physicians, and Teaching Hospitals: Review and Dispute Process Ends August 27

Physicians and teaching hospitals can now register in the Open Payments system to review and dispute data submitted by applicable manufacturers prior to public posting on September 30. At this time, physicians and teaching hospitals should review and initiate any disputes they may have regarding the data reported about them by applicable manufacturers.

Two key activities will take place during the review, dispute, and correction period:

- Before CMS releases any data publicly, physicians and teaching hospitals (who are registered in CMS’ Enterprise Portal and the Open Payments system) may review and, if necessary, initiate disputes relating to data submitted about them; and,
- Applicable manufacturers will analyze these disputes and work with physicians and teaching hospitals to come to agreement on any necessary corrections.

In order to review or dispute data submitted by industry for the 2013 reporting period, physicians must be registered and have reviewed any data reported about them on or before August 27, 2014.

To assist physicians, the USC Office of Compliance has developed step-by-step instructions that have been provided to all clinical department administrators as well as the faculty affairs office for distribution to physicians.

For additional information and to access the CMS Open Payments page for physicians, please go to: http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Physicians.html

OCR Levies Nearly $2 Million in HIPAA Fines for Stolen Unencrypted Laptops

On Tuesday, April 22, 2014, the U.S. Department of Health and Human Services Office for Civil Rights ("OCR") announced that Concentra Health Services Inc. ("CHS") and QCA Health Plan Inc. ("QCA") have agreed to pay a total of $1,975,220, collectively, to resolve potential violations of the Health Insurance Portability and Accountability Act ("HIPAA") Privacy and Security Rules stemming from the theft of unencrypted laptops. The clear message from both settlements is that OCR expects covered entities to
encrypt mobile devices that store electronic Protected Health Information ("ePHI").

These enforcement actions highlight the vulnerability of unencrypted laptop computers and other mobile devices and serve as a reminder of the significant risks they pose to the security of patient information. In response to these two incidents, Susan McAndrew, OCR's deputy director of health information privacy, emphasized that "Covered entities and business associates must understand that mobile device security is their obligation," and that "[OCR's] message to these organizations is simple: encryption is your best defense against these incidents."

USC has made it a requirement that laptops be encrypted, as referenced in the April 2009 Memo. In addition, USC has a policy regarding the storage and use of ePHI on mobile devices and removable media: http://policy.usc.edu/files/2014/02/CLIN-206-Minimum-Security-Standards-for-ePHI-for-Keck.pdf

You can read the full press release from the Department of Health and Human Services Office for Civil Rights here: http://www.hhs.gov/news/press/2014pres/04/20140422b.html

DOJ Filing Makes Clear That Current FCA Investigation Focuses on POD, Associated Hospital and Individual Doctor

On February 7, 2014, the United States Department of Justice ("DOJ") filed an application for summary enforcement ("Application") of a civil investigative demand ("CID") against Dr. Aria Sabit in the U.S. District Court for the Eastern District of Michigan. This inquiry demonstrates prosecutors' view that investment interests by physicians in Physician-Owned Distributors ("PODs") may constitute kickbacks under the Anti-Kickback Law ("AKL"), and that the target of investigations may not only be individual physicians, but the PODs and even the hospitals that order POD devices.

The DOJ served the CID on Dr. Sabit in August 2013, seeking information in connection with its broader investigation of Reliance Medical Systems, LLC ("Reliance"), which historically operated as a POD. Dr. Sabit was an investor in Apex Medical Technologies, LLC ("Apex"), a subsidiary of Reliance. During the period of his ownership in the POD, the DOJ alleges that his orders of Reliance products "increased dramatically."