

HHS Begins Flexing HIPAA Enforcement Muscles

BY DINETIA M. NEWMAN AND
MICHEL M. MARCOUX

Earlier this year, the United States Department of Health and Human Services, Office for Civil Rights (HHS) both enforced and settled allegations of Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule violations. In a first time imposition of civil monetary penalties (CMP) for HIPAA Privacy Rule violations, HHS publicized on February 22, 2011, its \$4.3 million CMP against Cignet Health of Prince George's County, Maryland (Cignet), operator of a family practice physician group with four Maryland locations and a health insurance plan (Cignet Health Plan). Two days later, HHS, General Hospital Corporation and Massachusetts General Physicians Organization, Inc. (the latter two entities collectively referred to as Mass General) entered into a Resolution Agreement, resulting in Mass General's paying the federal government \$1 million dollars in settlement of a HIPAA Privacy Rule complaint.

Cignet Privacy Rule Violations and CMPs

HHS based its enforcement action on Cignet's inactions between August 2008 and April 7, 2010, concluding that Cignet breached the HIPAA Privacy Rules by failing to provide 41 individuals timely access to copies of their medical records (45 CFR 164.524(b)(2)), by failing to cooperate with HHS through the Office for Civil Rights' (OCR) investigation of patient complaints (45 CFR 160.310) and by not correcting the violations within 30 days of when Cignet knew or with the exercise of reasonable diligence would have know of the violations (45 CFR 160.404(b)(2)(iv)).

Sanctions under the HIPAA Privacy Rule (enhanced by statutory amendments in the Health Information Technology for Economic and Clinical Health Act (HITECH Act), 42 U.S.C. 1320d-5)) authorize HHS through OCR to impose CMPs in varying amounts, from not less than \$100 to not less than \$50,000 for each violation of the HIPAA Privacy Rule occurring on or after February 18, 2009 as long as the total annual amount imposed does not exceed \$1.5 million. Prior to HITECH's enactment, HHS' authority was limited to a per violation penalty of \$100 and an annual cap of \$25,000. The HIPAA Privacy Rule requires covered entities

such as Cignet to provide to individuals of their medical records within 30 to 60 days from the individual's request.

In imposing CMPs, HHS concluded that Cignet's inactions were due to "willful neglect" of its HIPAA Privacy Rule obligations, penalizing Cignet \$100 per each day (13,516 days) that Cignet failed to give patients their requested medical records (after applicable pre- and post-HITECH annual caps, CMPs totaling \$1.3 million) and \$50,000 per day, counting each day (7,478 days) as a separate Privacy Rule violation, for failure to cooperate (after applicable pre- and post-HITECH annual caps, CMPs totaling \$3 million).

Mass General Resolution

The Mass General covered incident resulted from a complaint to OCR after an employee removed patient records from the premises of Mass General's Infectious Disease Associates outpatient practice and inadvertently left those documents on the subway train. The documents included billing and encounter forms with the name, date of birth, medical record number, health insurer and policy number, diagnosis and name of the provider for 66 patients and daily office schedules for three days containing the names and medical record numbers of 192 patients, including patients with HIV/AIDS.

In addition to requiring the immediate payment of \$1 million dollars, HHS required Mass General to put in place a comprehensive, three year Correction Action Plan (CAP). The CAP required Mass General to develop policies and procedures regarding the physical removal and transportation of documents containing PHI, to encrypt of laptops and USB drives as well as to establish processes for distributing and updating the policies and procedures; to implement workforce training; to designate a monitor; and to semi-annually report to HHS.

What Does This Mean For Covered Entities

Although the two February announcements may not reflect a more

Continued on page 14

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Medical Construction, *continued from page 12*

ily zone features a recliner, sleeper sofa, large wardrobe, a patient education/entertainment system, and a small safe for valuables. Most patient rooms will also include a spacious private bathroom.

Each patient floor will have a family kitchen with a refrigerator and microwave, a laundry room, and sub-waiting rooms with natural lighting. Consultation rooms for private conversations are located outside the patient rooms.

To ensure the patient rooms are as efficient and family-friendly as possible, "pretend rooms" have been built to provide a means of evaluating the relation of the three "zones" to make sure they work together efficiently and that all elements of the room are placed correctly.

"We felt strongly about having mock ups of the key rooms, because we thought that was the best way the team members could translate what they heard from staff, patients, and families," McDevitt says. "We want to make sure the staff can care for the patient adequately in the rooms and that the parents are comfortable."

Construction of the new hospital is providing about 1,746 jobs and \$70.6 million in payroll to local contractors, bringing a significant economic boost to the State of Alabama, Jefferson County, and the City of Birmingham. In addition, Children's Hospital is poised to become the first hospital in the state to attain Leadership in Energy and Environmental Design (LEED) certification with the new construction. Incorporating green design into the building of a hospital typically adds two to four percent to the construction costs. Such costs for this project will be underwrit-

ten by a portion of a \$10 million gift from Birmingham-based McWane, Inc. and the McWane Foundation.

"It's not about the certification as much as the decisions we make on the project that leave as small a footprint as possible in creating a healthy facility for the children," McDevitt says. "It is all about the future and we want to leave the kids we treat an inheritance of a healthy environment."

Cooper Green Mercy Hospital

Renovation of the Emergency Department at Cooper Green Mercy Hospital is scheduled for completion at the end of May. Expansion of current facilities will address patient growth and enhance patient care.

Cleo Kathryn Gorman, Marketing Senior Associate with project architect TRO Jung/Brannen, says construction includes the creation of a more open waiting room that provides additional seating. The addition of a second triage room will help the staff assess the acuity of emergency patients. "The additional room will help to make the main Emergency Department more efficient in delivering emergency care," Gorman says.

Phase I of the project created a temporary waiting room in a space formerly used for diagnostic equipment. Seating there equals that of the prior waiting area where renovations were allowed to proceed for waiting room expansion and installation of a new roof-mounted air handler.

Other functional areas of the Emergency Department will remain in their current locations, including admitting and security, which will remain adjacent to the waiting room.

HHS Begins Flexing HIPAA Enforcement Muscles, *continued from page 9*

aggressive HHS and additional enforcement actions with less egregious and unusual fact patterns may reveal more about HHS' intent to use its heightened HITECH sanction authority, HHS' actions do offer a number of takeaways.

- First, HHS' actions remind covered entities that: (1) HHS has 6 years to investigate and impose CMPs and (2) even though final regulations have not been issued for the majority of HITECH's enactments, an interim final rule increasing penalties for HIPAA violations and strengthening HHS' enforcement authority and the breach notification final rule are final.

- Second, by concluding that Cignet's multiple failures and inactions constitute "willful neglect", HHS has provided an example of what constitutes "conscious, intentional failure or reckless indifference to [HIPAA obligations]."

- Third, the CAP imposed by HHS offers a roadmap for covered entities and business associates to prevent workforce incidents from resulting in

Privacy Rule and HIPAA security rule violations. Encryption and/or other security measures could significantly improve covered entities' and business associates' required compliance with HIPAA Privacy (and security) Rules and avoid their payment of costly CMP and settlement amounts.

- Further, despite HITECH's increased governmental enforcement capabilities and business associates' HIPAA Privacy Rule compliance, the lack of final regulations has lulled many covered entities and business associates along with their workforces into complacency and non-compliance. HHS' recent decisions should be a wake-up call to reinvigorate HIPAA training, monitoring and compliance activities.



Dinetia M. Newman,
 Partner, Balch &
 Bingham LLP, Jackson,
 Mississippi, and **Michel**
M. Marcoux, Associate,
 Balch & Bingham LLP,
 Birmingham, Alabama