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Health Headlines

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HHS Imposes $4.3 Million CMP for HIPAA Privacy Rule Violations and Announces $1 Million Settlement – Last week, the U.S. Department of Health and Human Services (HHS) announced two major actions in the HIPAA enforcement arena: (1) the imposition of $4.3 million in civil monetary penalties (CMPs) against Cignet Health Care, which marks the first ever imposition of CMPs by HHS against a covered entity for HIPAA Privacy Rule violations; and (2) a $1 million settlement with Mass General to resolve alleged HIPAA Privacy Rule violations.

Subject to certain limitations under 42 U.S.C. § 1320d-5(b), HIPAA authorizes the Secretary of HHS to impose CMPs against any covered entity that violates a provision of the HIPAA administrative simplification provisions, which include the Privacy Rule regulations under 45 C.F.R. Part 160 & Part 164, Subparts A and E. The HITECH Act, enacted on February 17, 2009, as part of the American Recovery and Reinvestment Act of 2009, dramatically increased the amount of authorized penalties. Prior to February 18, 2009, the Secretary could impose on any person who violated HIPAA a penalty of not more than $100 for each violation, up to a $25,000 calendar year cap for all violations of an identical requirement or prohibition. As amended by HITECH, the Secretary may impose a range of CMPs of not less than $100 to more than $50,000 for each violation, subject to an increased calendar year maximum sanction of up to $1.5 million for all violations of an identical requirement or prohibition.

1. HHS Imposes $4.3 Million Civil Monetary Penalty Against Cignet.

On February 22, 2011, HHS announced the imposition of $4.3 million in CMPs against Cignet Health Center (Cignet) for violations of the HIPAA Privacy Rule. Approximately $1.3 million of the total penalty is due to Cignet's failure to provide 41 individuals access to their medical records, as required by 45 C.F.R. § 164.524, and the remaining $3 million is for Cignet's failure to cooperate with an investigation, as required by 45 C.F.R. § 160.310(b).

The HHS Office for Civil Rights (OCR) notified Cignet of the proposed $4.3 million in CMPs and the findings of fact forming the basis for the imposition of the penalties in an October 20, 2010 Notice of Proposed Determination (Proposed Determination). According to the Proposed Determination, Cignet failed to respond to 41 individuals who requested access to their medical records between September 2008 and October 2009. Thirty-eight of those individuals filed complaints with OCR, and OCR initiated an investigation of each complaint.

According to the Proposed Determination, Cignet did not respond to OCR's written notifications of the investigations and multiple follow-up attempts to contact Cignet, did not produce the records during the investigations as required, and did not respond to a subpoena demanding that Cignet produce records in connection with 11 of the investigations. Cignet eventually produced the records, but OCR found that Cignet made no other efforts to resolve the complaints through informal means. OCR found that Cignet's failure to cooperate with the 27 investigations underway as required by 45 C.F.R. § 164.310(b) was due to "willful neglect," which HIPAA defines as "conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated." 45 C.F.R. § 160.401.

OCR calculated the penalties for Cignet's failure to provide records at $100 per record per day, totaling $1.3 million. OCR calculated the penalties for Cignet's failure to cooperate at $50,000 per day per violation, totaling well over the statutory yearly maximum of $1.5 million. Accordingly, OCR reduced the 2009 and 2010 penalties to $1.5 million per year, resulting in the $3 million in total penalties for failure to cooperate.

OCR finalized the $4.3 million proposed CMPs on February 4, 2011. According to the Notice of Final Determination, OCR finalized the penalties because Cignet did not timely request a hearing in accordance with the instructions in the Proposed Determination or otherwise settle the matter as permitted by 45 C.F.R. § 160.416. In addition, OCR informed Cignet that it did not have a right to appeal the determination due to its failure to timely request a hearing. *See* 45 C.F.R. § 160.422.

A copy of the HHS Press Release is available by clicking here. A copy of the Proposed Determination is available by clicking here. A copy of the Final Determination is available by clicking here.

2. Mass General Agrees to Pay $1 Million to Settle Potential HIPAA Violations.

On February 24, 2011, HHS announced that The General Hospital Corporation and Massachusetts General Physicians Organization, Inc. (Mass General) has agreed to pay $1,000,000 to settle potential violations of the HIPAA Privacy Rule. According to the Resolution Agreement (the Agreement) between Mass General and OCR, the incident giving rise to the Agreement involved the loss of protected health information (PHI) of 192 patients of Mass General's Infectious Disease Associates outpatient practice (the Practice), some of whom have HIV/AIDS.

In order to work from home, a Mass General employee removed from the Mass General premises billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis, and name of provider for 66 patients, as well as the Practice's daily office schedules for three days containing the names and medical record numbers of 192 patients. While commuting back to work several days later, the employee left the documents on the subway, and they were not recovered. OCR opened its investigation of Mass General after a patient whose PHI had been lost during the incident filed a complaint.
According to the HHS press release, OCR's investigation indicated that Mass General potentially violated the HIPAA Privacy Rule by failing to implement reasonable and appropriate safeguards to protect the PHI when removed from Mass General's premises, and by impermissibly disclosing PHI. Mass General did not admit any liability or wrongdoing by entering the Agreement.

In addition to the $1 million settlement payment, Mass General agreed to enter into a Corrective Action Plan (CAP), which requires Mass General to:

- Develop and implement a comprehensive set of policies and procedures that ensure PHI is protected when removed from Mass General's premises;
- Provide specific training on the policies and procedures to all workforce members who have access to PHI; and
- Designate the Director of Internal Audit Services of the Partners HealthCare System, Inc. to serve as the Monitor who will conduct assessment's of Mass General's compliance with the CAP and render semi-annual reports to HHS for a 3-year period.

A copy of the HHS press release is available by clicking here. A copy of the Resolution Agreement and CAP is available by clicking here.

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CMS Considers Withdrawing Rule Requiring Physician Signature on Lab Requisitions – CMS is expected to withdraw its new policy requiring physicians to sign requisitions for clinical laboratory tests. In November 2010, CMS finalized its policy, to be effective January 1, 2011, requiring all requisitions for clinical diagnostic laboratory tests paid on the basis of the clinical laboratory fee schedule to be signed by a physician or qualified nonphysician practitioner. 75

Fed. Reg. 73170, 73480-83 (Nov. 29, 2010). CMS defines a requisition as "the actual paperwork, such as a form, which is provided to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient." 75 Fed. Reg. at 73483. However, in response to concerns from laboratories regarding the burdens of this new requirement, CMS delayed enforcement and said it would "spend the first quarter of 2011 developing educational and outreach materials that will be posted on the CMS website." The rule was expected to be enforced beginning April 1, 2011.

Recently, bipartisan letters from both the United State House of Representatives and Senate were sent to CMS requesting that CMS delay enforcement of the rule for an additional nine months, as "more time is needed for CMS to work with physicians and the lab community on this rule and to discuss the potentially serious implications on patient care and business practice." Both the House and the Senate cautioned that situations would arise in which urgent laboratory services were needed but a physician was unavailable for signature. The letter from the House is available by clicking here, and the letter from the Senate is available by clicking here.

Two clinical laboratory associations, which have been discussing the burdens of the rule with CMS, are reporting that CMS will rescind the rule.

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March 7 Deadline for Requesting Corrections to Medicare Wage Index Data – On February 22, 2011, CMS released the FFY 2008 public-use files of each PPS hospital's wage data to be used in calculating the FY 2012 Wage Index. The deadline for hospitals to submit correction requests and supporting documentation regarding any claimed errors in this February wage index data is March 7, 2011. Medicare contractors must receive all requests and documentation by March 7, 2011.

The public-use files are available on the FY 2012 Wage Index Home Page, on the Acute Inpatient PPS section of the CMS website, available by clicking here. The FY 2012 Wage Index Development Timetable is available by clicking here.

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CMS Launches Medicaid RAC Website – Earlier this month, CMS launched a State Medicaid Recovery Audit Contractor (RAC) "At-A-Glance" website. The website provides a map that summarizes the status of each jurisdiction's RAC program. Information includes whether CMS has received a state plan amendment (SPA), whether an exception has been requested, and the type of RAC fee structure. CMS will update the website on an ongoing basis.

Pursuant to Section 6411 of the Patient Protection and Affordable Care Act, states are required to establish a Medicaid RAC program in order to help identify and recover Medicaid overpayments, among other things. States must submit a SPA that addresses some of the key elements of their RAC program as set forth in the proposed rule, available at 75 Fed. Reg. 69037 (Nov. 10, 2010). According to a CMS bulletin dated February 1, 2011 (CPI-B 11-03), the original Medicaid RAC implementation date of April 1, 2011 has been delayed until a final rule is issued, which will be later this year.

Based on the website, all states and U.S. territories have submitted their Medicaid SPA except for the District of Columbia, and CMS has approved 10 SPAs. The At-A-Glance website is available by clicking here, and the proposed rule is available by clicking here.

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IRS Delays Form 990 Filing Season for Certain Tax-Exempt Hospitals – In Announcement 2011-20 (the Announcement), the Internal Revenue Service (the IRS) announced that hospital organizations that are required to file Schedule H with their 2010 IRS Form 990 must not file the 2010 Form 990 before July 1, 2011, regardless of whether the hospital organization files an electronic return or a paper return. In addition, the IRS granted an automatic three-month extension of time to file the 2010 Form 990 to tax-exempt hospitals usually required to file their IRS Form 990 for the 2010 tax year before August 15, 2011. This automatic extension of the filing due date does not apply to any other tax-exempt organization required to file Form 990.

The filing delay results from the IRS's need for more time to implement changes to forms and systems to take into account the new Section 501(r) requirements (including the new community health needs assessment, financial assistance policy, limitation on charges and billing, and collections provisions) enacted as part of the Patient Protection and Affordable Care Act of 2010.

The IRS granted automatic extensions only to tax-exempt organizations that attached Schedule H to their 2008 and/or 2009 Form 990 returns and had tax years ending in the months of December, January, or February (*i.e.*, with Form 990 return due dates in May, June, and July, respectively). These hospital organizations are not required to file IRS Form 8868 (*Application for Extension of Time To File an Exempt Organization Return*) in order to take advantage of the automatic extension.

Importantly, however, recently formed hospital organizations that did not file Form 990 Schedule H for tax year 2008 or 2009 and that believe they are entitled to the extension of time under the Announcement are encouraged to file IRS Form 8868 (*Application for Extension of Time To File an Exempt Organization Return*) to reduce the risk that they may incorrectly receive a penalty notice from the IRS.

No late-filing penalties will apply to a tax year 2010 Form 990 (with Schedule H attached) filed by a hospital covered by the Announcement on or before the three-month extended due date. A hospital organization that later determines that it needs additional time beyond the automatic three-month extension period to file its 2010 Form 990 may request an additional three-month extension of time by filing IRS Form 8868, Part II. A hospital organization covered by the Announcement may receive no more than a six-month extension of time to file for its 2010 tax year.

The IRS Announcement is available by clicking here. The FAQs about the Announcement are available by clicking here.

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New FDA Rule on Medical Device Data Systems Carries Implications for Healthcare Facilities – On February 15, 2011, the FDA published a final rule that clarifies that Medical Device Data Systems (MDDSs) are regulated by the FDA and establishes the regulatory requirements for these medical devices. *See* 76 Fed. Reg. 8637 (Feb. 15, 2011). Healthcare facilities and users should be aware that they will be deemed to be manufacturers subject to FDA requirements if they:

- develop their own software protocols or interfaces for medical devices that have an intended use consistent with a MDDS;
- modify or reconfigure a commercially available MDDS outside the original manufacturer's specifications either for the user's clinical use or for commercial distribution; *or*
- add to or modify any non-MDDS hardware or software to enable the transfer, storage, conversion according to preset specifications, or display of medical device data for use in clinical practice.

FDA defines an MDDS as a device intended to perform one or more of the following uses, without controlling or altering the functions of any connected medical devices: (1) the electronic transfer of medical device data; (2) the electronic storage of medical device data; (3) the electronic conversion of medical device data from one format to another format in accordance with a present specification; or (4) the electronic display of medical device data. The rule excludes from the MDDS definition any devices intended to be used in connection with active patient monitoring.

If a healthcare facility is a manufacturer of a MDDS, it is subject to FDA requirements for Medical Device Reporting (*i.e.*, adverse event reporting to FDA), corrections and removals (*i.e.*, recalls) reporting and recordkeeping, establishment registration, and device listing. It also must comply with good manufacturing practices and product design requirements codified in FDA's Quality System Regulation.

The new rule becomes effective April 16, 2011. After that time, FDA will begin active regulation of MDDS manufacturers and use its existing enforcement authorities and policies to enforce requirements applicable to MDDS medical devices. Thus, it is prudent for healthcare facilities to become familiar with the definition of a MDDS under the new rule, develop procedures to identify whether the facility or user is modifying a MDDS as a manufacturer, and ensure

compliance with FDA requirements.

A recent King & Spalding client alert on this new rule is available by clicking here.

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CMS Issues Guidance to State Medicaid Directors Clarifying Maintenance of Effort Requirements – On February 25, 2011, CMS issued a letter and accompanying Questions & Answers (Q&As) to state Medicaid directors clarifying certain aspects of the maintenance of effort (MOE) provisions in the Affordable Care Act. The Act's MOE provisions generally prohibit states from altering their Medicaid and CHIP coverage rules, pending implementation of the changes mandated by the Affordable Care Act in 2014 (Medicaid) and 2019 (CHIP). Recently, some states have requested waiver of the MOE requirements, in light of financial pressures faced by many states, but the HHS Secretary has stated that she lacks the authority to do so. The February 25 letter and Q&As, which are available by clicking here, provide guidance as to ways states may be able to reduce expenditures while still complying with the MOE requirements.

Specifically, the Q&As address three aspects of the MOE provisions: (1) the MOE exemption for higher-income adult populations in states experiencing budget deficits; (2) the implications of the MOE provision on Section 1115 demonstration projects; and (3) how premiums are treated under the MOE requirements.

MOE Exemption for Higher-Income Adults

If a state submits a certification to the Secretary that it has (or projects) a budget deficit in a given fiscal year, the state may amend its State Plan and alter Medicaid eligibility requirements for adults with incomes above 133% of the federal poverty level, as long as the adults are not Medicaid-eligible on the basis of pregnancy or disability. However, the Q&As caution that states should be careful when considering eligibility changes prior to June 30, 2011, because the MOE provisions of the American Recovery and Reinvestment Act (Recovery Act) do not contain a similar budget deficit exception, and a violation could result in the loss of increased federal matching funds available through the Recovery Act.

Implications for Section 1115 Demos

The Q&As clarify that the MOE provisions *do* apply to Section 1115 waiver/demonstration projects, but *do not* require states to renew a section 1115 demonstration upon its specified expiration date. The Q&As also specify that if Federal costs under a Section 1115 demonstration could exceed what is permitted under the demonstration's budget neutrality agreement, the state may use procedures specified in the special terms and conditions to change its program to maintain budget neutrality, without violating the MOE requirements.

Treatment of Premiums Under MOE Requirements

The Q&As specify that the following are *not* MOE violations for Medicaid and CHIP: (1) automatic premium increases explicitly specified in a State plan or demonstration as of July 1, 2008 (Medicaid) and March 23, 2010 (CHIP); (2) the adoption (through State plan or demonstration amendments) of certain inflation-related adjustments to premiums in effect as of July 1, 2008 (Medicaid) or March 23, 2010 (CHIP); and (3) the adoption of premiums for new coverage groups, as long as the new coverage and premium amounts are consistent with other provisions of law.

The agency's interpretation with respect to premiums differs from prior CMS guidance relating to the MOE provisions under the Recovery Act, in which CMS indicated that premium increases or imposition of new premiums was inconsistent with the Recovery Act's MOE provisions. In the Q&As, the agency states that premium increases are still generally prohibited under the Recovery Act, although the Recovery Act's MOE provisions will expire on June 30, 2011.

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CMS Announces Plans for A/B MAC Round II Procurements – CMS has announced plans to consolidate the current 15 A/B Medicare Administrative Contractor (MAC) jurisdictions into 10 jurisdictions in the second round of re-bidding of

the MAC contracts beginning in late 2011. In addition to consolidating the existing 15 A/B MAC jurisdictions into 10 jurisdictions, CMS intends to re-designate the 10 jurisdictions by "letter" rather than by "number." CMS expects to complete the awarding of Round II contracts and the resulting consolidation and renaming of MAC jurisdictions by 2016.

Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to replace the Medicare claims payment contractors, fiscal intermediaries (FIs) and carriers, with new administrative entities called MACs. The MMA requires CMS to re-bid each of its MAC contracts every five years. Because the first MAC contracts were awarded by CMS in 2006, the contracts awarded in the first cycle of Round I procurements are due to be re-bid by the end of this year. At present, CMS has fully implemented 9 of the 15 A/B MAC contracts, while 6 of the contracts have not yet been implemented due to bid protests or procurement corrective actions.

In the Round II re-bidding of the MAC contracts, CMS will create the following consolidated A/B MAC jurisdictions:

- Jurisdiction F, comprised of former jurisdictions 2 and 3 (covering Alaska, Washington, Oregon, Idaho, North Dakota, South Dakota, Montana, Wyoming, Utah, and Arizona);
- Jurisdiction G, comprised of former jurisdictions 5 and 6 (covering Minnesota, Wisconsin, Illinois, Kansas, Nebraska, Iowa, and Missouri);
- Jurisdiction H, comprised of former jurisdictions 4 and 7 (covering Louisiana, Arkansas, Mississippi, Texas, Oklahoma, Colorado, and New Mexico);
- Jurisdiction I, comprised of former jurisdictions 8 and 15 (covering Kentucky, Ohio, Michigan, and Indiana); and
- Jurisdiction K, comprised of former jurisdictions 13 and 14 (covering New York, Connecticut, Massachusetts, Rhode Island, Vermont, Maine, and New Hampshire).

Five A/B MAC jurisdictions will not be further consolidated: jurisdiction 1 will become new jurisdiction E (covering California, Hawaii, Nevada, Pacific Islands); jurisdiction 9 will become new jurisdiction N (covering Florida, Puerto Rico, US Virgin Islands); jurisdiction 10 will become new jurisdiction J (covering Alabama, Georgia, Mississippi, Tennessee); jurisdiction 11 will become new jurisdiction M (covering North Carolina, South Carolina, Virginia, West Virginia); and jurisdiction 12 will become new jurisdiction L (covering Delaware, Maryland, Pennsylvania, New Jersey, Washington, D.C.).

The consolidation of A/B MAC jurisdictions will commence with the re-bidding of implemented A/B MAC contracts and will be completed over the next five years. Round II solicitations for the jurisdictions to be consolidated will specify a target date for implementing the existing jurisdictional workload in each pairing, which will coincide with the end date of the existing A/B MAC whose contract will expire first. The new solicitations will also designate a target date for integrating the second jurisdictional workload in each pairing into the consolidated A/B MAC, which will coincide with the second jurisdiction's contract end date.

More information regarding MAC contracting reform and the consolidation of the MAC jurisdictions is available by clicking here and here. A map showing the consolidated MAC jurisdictions is available by clicking here.

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King & Spalding 20th Annual Health Law and Policy Forum – King & Spalding's 20th annual Health Law and Policy Forum will be held this year on March 14 at the Four Seasons Hotel in Atlanta. Please be on the lookout for additional communications soon that will provide details on the specific content of the program.

Health Headlines – Editor:

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