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HHS FOCUSES ON PRIVACY WITH THE FINAL HIPAA REGULATIONS AND A NEW GUIDANCE DOCUMENT

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The health care community received two gifts from the Department of Health and Human Services (HHS) last week. On Thursday, January 17, 2013, HHS issued the prepublication version of the long awaited HIPAA Final Rules, implementing changes as provided for in the Health Information Technology for Economic and Clinical Health (HITECH) Act. The regulations are scheduled for publication in the January 25, 2013 Federal Register and may be accessed at <https://www.federalregister.gov/public-inspection>. At a hefty 563 pages, the regulations appear to touch on all aspects of HIPAA-privacy, security, breach notification, and enforcement.

In a reaction to the Sandy Hook tragedy, the Office of Civil Rights issued guidance on disclosing protected health information when a provider believes that there is a threat to the safety of another person. While this guidance did not alter past interpretations of that particular privacy provision, it did clarify the boundaries of such disclosures. This guidance may be accessed at <http://www.hhs.gov/ocr/office/index.html>.

THE FINAL HIPAA REGULATIONS

WHAT THE REGULATIONS DO

Modifies the HIPAA Privacy, Security, and Enforcement Rules in accordance with the HITECH Act

A cursory review of the Final Rules confirms a larger obligation on the part of business associates and their subcontractors to comply with the privacy, security and breach notification rules. HHS also finalized new rules (significantly modifying the proposed rule published at 75 FR 40868 (July 14, 2010)) for marketing disclosures. The Final Rules require an authorization for all treatment and health care operations communications if the covered entity receives financial remuneration from a third party whose product is being marketed for purposes of making the communications. The Final Rules also largely adopt the proposed rulemaking for the sale of protected health information (PHI) and fundraising with some changes.

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The Final Rules also adopt the proposed modification to 45 C.F.R. 164.520(b)(1)(ii)(E), addressing the statements that must be included in a Notice of Privacy Practices (NPP). Examples of required notifications include an individual's right to the restriction of disclosures when the individual pays out of pocket for the service and the right to be notified following the breach of unsecured PHI.

Finalizes the Breach Notification Rules, replacing the Interim Final Rule published at 74 FR 42740 (Aug. 24, 2009)

The Final Rules provide much needed clarification related to the risk assessment. The new breach guidance replaces the vague substantial risk of harm test with a more guided, objective approach. The assessment focuses on four factors: (1) the nature and extent of the PHI involved; (2) the unauthorized person who impermissibly used or to whom the impermissible disclosure was made; (3) whether the PHI was actually acquired or viewed; and (4) the extent to which the risk has been mitigated.

Revises the HIPAA Privacy Rule, increasing privacy protections for genetic information in accordance with the Genetic Nondiscrimination Act of 2008 (GINA)

The Final Rules do not offer any unexpected surprises related to the GINA revisions. HHS adopts the proposed definitions and the prohibition on a health plan's use or disclosure of genetic information for underwriting purposes, except for issuers of long term care policies.

Adopts miscellaneous further changes for purposes of workability and flexibility

For example, the Final Rules modified the timeliness requirements for granting an individual the right of access and to obtain a copy of his/her PHI. For off-site records, the Final Rules remove the provision allowing covered entities 60 days for granting access and/or a copy of off-site records with a 30-day extension, or, up to 90 days to comply with the individual's request. Under the Final Rules, a covered entity must grant access and/or a copy of off-site records within 30 days of the individual's request with a 30-day extension available when necessary, or, within 60 days of the request.

HHS also offers guidelines for the imposition of penalties and compliance reviews. While there is much more to digest, Kansas providers received a welcome clarification to state law. Under state law, the right of an heir to obtain the records of a deceased patient has always been unclear. The KHITE Act conformed state law with HIPAA, and the new regulations make clear that next-of-kin may obtain the PHI of their deceased relative to the extent that they were involved in their care or payment for care.

WHAT THE REGULATIONS DO NOT DO

The HIPAA Final Rules do not address the accounting of disclosures requirement under Section 13405 of the HITECH Act, which were the subject of proposed rulemaking published at 76 FR 31426 (May 31, 2011). In the NPRM, HHS proposed to revise 45 C.F.R. 164.528 by dividing it into two separate rights: (1) the right to an accounting of disclosures and (2) the right to an access report. The proposed right to an access report, documenting every individual who accesses the individual's electronic records, has drawn much criticism from health care providers related to the burdensome nature of compliance. For now, HHS has not offered any further guidance or finalized its rule related to this issue.

Compliance Deadline

The HIPAA Final Rules are effective as of March 26, 2013. HHS has given covered entities and business

associates an additional 180 days, or until September 23, 2013, to update HIPAA policies and procedures and to otherwise come into compliance with the Final Rules. There is one important caveat to this 180-day compliance period. This does not impact a covered entity's obligation to comply with the breach notification requirements under the HITECH Act for breaches of unsecured PHI. The HITECH Act applies to breaches of unsecured PHI discovered on or after September 23, 2009. Therefore, covered entities are still obligated to meet the breach notification requirements under HITECH and the Interim Final Rule.

Foulston Siefkin LLP is in the process of preparing HIPAA policies and procedures and other training materials in accordance with the Final Rules requirements.

FOR FURTHER INFORMATION

If you have questions or want more information, you should contact your legal counsel to ensure compliance with the Final Rules. If you do not have regular counsel, Foulston Siefkin LLP would welcome the opportunity to work with you to specifically meet your business needs. **Brooke Bennett Aziere** or **Marta Fisher Linenberger** are available to assist you. Brooke Bennett Aziere can be reached at 316.291.9768 or **baziere@foulston.com**. Marta Fisher Linenberger can be reached at 785.354.9415 or **mlienberger@foulston.com**. If you are looking for general health care counsel you may contact **Scott Palecki** at 316.291.9578 or **spalecki@foulston.com**.

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