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U.S. Department of Health and Human Services (“HHS”) Issues Final HIPAA Omnibus Rule

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The **U.S. Department of Health and Human Services (“HHS”)** recently announced its issuance of the highly-anticipated regulations or Final Omnibus Rule (“Rule”) relating to the modification of the HIPAA Privacy, Security, and Enforcement rules under the Health Information Technology for Economic and Clinical Health Act (“the HITECH Act”). 78 Fed.Reg. 17 Part II (January 25, 2013) modifying 45 CFR Parts 160, 162, 164. The Final Rule, 78 Fed.Reg. 17 Part II, 563 pages in length, makes significant changes of which all providers need to be aware. A complete examination of the sweeping changes cannot be done in one article, so we will make a general summary of the most important changes.

The new HIPAA Rule extends certain provisions of the HIPAA Privacy, Security, and Breach of Notification Rules to Business Associates (“BA”). This means that a BA is now legally accountable for compliance with HIPAA rules.

Moreover, the definition of who qualifies as a BA has expanded to cover new entities and persons. Now, a BA includes health information organizations, which is left undefined in the regulation, e-prescribing gateways, data transmission entities that routinely access PHI, and vendors of PHI records. However, a person or entity does not become a BA simply by contracting with the covered entity and entering into a Business Associates Agreement (“BA Agreement”). Further, subcontractors or agents working on behalf of BA’s are now considered a BA.

The Final Rule has also added new requirements for the content of BA Agreements. For example, all BA Agreements must include specific provisions detailing how the BA is to report breaches of unsecured PHI to covered entities.

Due to the Final Rule’s lengthy provisions regarding BAs and expansion of the definition of a BA, it is crucial that covered entities identify persons and entities that qualify as a BA and make sure that his/her current or future agreement is in compliance with the new rules.

In addition to the expansion of the BA rules, the Final Rule expands patients’ rights. For instance, a covered entity must now provide a patient access to his/her “readily producible” electronic PHI with access to the electronic information upon that patient’s request. As a result, a covered entity needs to evaluate their electronic systems’ ability to produce or give access to this information. In addition, patients that have paid out of pocket for healthcare services can restrict the disclosure of information about those services to health plans. Also, patient’s privacy protections were strengthened through increased restrictions on the disclosures of PHI. Thus, covered entities need to revise their notices of privacy practices to include the new patient rights under the Final Rule.

Lastly, the Final Rule changes how covered entities and BAs may use and disclose PHI. The new rule significantly changes to how PHI can be used and disclosed for marketing, research, and fundraising purposes. The rule also allows a patient to restrict disclosures for fundraising or marketing purposes. In addition, the new rule creates new limitations on the sale of PHI. Any arrangements that implicate these requirements should be reviewed and updated.

Since covered entities must comply with the Final Rule by September 23, 2013, covered entities should take prompt action to comply with these changes.



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