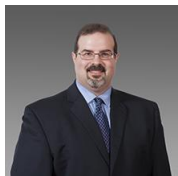


## HIPAA Recharged: HHS Releases Omnibus Final Rule

By Christopher Allman and Stephanie Ottenwess

On January 17, 2013, the U.S. Department of Health and Human Services Office of Civil Rights released the long-awaited final omnibus rule containing sweeping changes to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules (Final Rule). With these changes, health care organizations and business associates are going to be held to a stricter standard with respect to patients' protected health information, or PHI. The Final Rule strengthens the ability of HHS to vigorously enforce the HIPAA privacy and security protections, regardless of whether the information is being held by a health plan, a health care provider, or one of their business associates. The Final Rule also greatly enhances a patient's privacy protections, provides individuals new rights to their health information, strengthens the government's ability to enforce the law and increases penalties when there is a violation. The Final Rule is essentially comprised of four main sub-final rules: 1. Clarifications and modifications to HIPAA Privacy, Security, and Enforcement Rules, including: a. Making business associates (BA) of covered entities (CE), and their subcontractors, directly liable for compliance with certain HIPAA Privacy and Security Rule requirements. b. Expanding the definition of a BA to include an entity that "maintains" PHI, even if the BA does not access the information (i.e. medical records storage companies, or "cloud" storage) and no matter how far downstream from the CE the party may be. c. Making a CE liable, and possibly subject to civil money penalties, for the acts of BAs. d. Strengthening the limitations on the use and disclosure of PHI for marketing and fundraising purposes, and prohibiting the sale of PHI without individual authorization. e. Requiring modifications to, and redistribution of, a CE's notice of privacy practices. f. Modifying the individual authorization and other requirements to facilitate research and disclosure of child immunization proof to schools, and enabling access to a decedent's information by family members or others. 2. Changes to HIPAA enforcement in moving away from the voluntary compliance framework and incorporating an increased civil money penalty tiered structure. 3. Modifications to Breach Notification for unsecured PHI, including: a. Altering the definition of "breach" significantly from a subjective "risk of harm" standard to an objective "low probability that PHI has been compromised" standard. An impermissible use or disclosure of PHI is presumed to be a breach unless demonstrated that there is a low probability that PHI has been compromised. b. Requiring Breach notification in most situations, not just those that can cause harm. c. Revising notifications with breaches involving fewer than 500 affected individuals, by requiring notification to the Secretary within 60 calendar days after the end of the year in which the breach was discovered as opposed to when it occurred. 4. Clarifying that genetic information is protected under the HIPAA Privacy Rule and prohibiting most health plans from using or disclosing genetic information for underwriting purposes. The individual rights of patients are also expanded in important ways including: 1. Right to receive an electronic copy of their medical record on demand. 2. When paying by cash for services, having the right to instruct their provider not to share information with their health plan. The deadline to comply with the Final Rule is September 23, 2013. All CEs and BAs must take the opportunity now to ensure their current HIPAA policies and procedures and contracts are amended to account for the new regulations or take the time to develop the appropriate compliance plans and contracts.



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