



HIPAA's New Omnibus Rule Adopted

*“The Omnibus rule...strengthens the ability (of OCR)
to vigorously enforce the HIPAA Privacy and Security protections...”*

In January, the U.S. Department of Health and Human Services (HHS) adopted the “Omnibus Rule”, designed to strengthen the privacy and security protections for health information established under HIPAA. According to HHS, the new rule, based on statutory changes under the HITECH Act, will “help protect patient privacy and safeguard patients’ health information in an ever expanding digital age.”

It also strengthens the government’s ability to enforce the law. According to OCR Director Leon Rodriguez, “This final omnibus rule marks the most sweeping changes to the HIPAA Privacy and Security Rules since they were first implemented and also strengthen the ability of my office to vigorously enforce the HIPAA privacy and security protections. Penalties for noncompliance based on the level of negligence increased with a maximum penalty of \$1.5 million per violation.

In capsule form, the HIPAA Omnibus rule is comprised of four primary rules:

1. It makes Business Associates directly liable for compliance with certain HIPAA requirements,
2. It strengthens limitations on use of patient PHI for marketing and fundraising,
3. It prohibits the sale of patient PHI without written authorization individual patient,
4. It expands patients’ right to obtain electronic copies of their health information,
5. It restricts disclosure of patient out-of-pocket payment for treatment to health plans,
6. It modifies requirements, including individual authorization, to facilitate research and disclosure of child immunization proof to schools,
7. It enables family members and, in some cases, others to access decedent’s PHI,
8. It requires modification and redistribution of notice of privacy practices,
9. It changes and enhances HIPAA enforcement rules,
10. It replaces the Breach Notification “harm” threshold with a more objective standard, and
11. It prohibits most health plans from using or disclosing genetic information for underwriting purposes.

The final omnibus rule is based on statutory changes under the HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009, and the Genetic Information Nondiscrimination Act of 2008 (GINA) which clarifies that genetic information is protected under the HIPAA Privacy Rule and prohibits most health plans from using or disclosing genetic information for underwriting purposes.

The Rulemaking announced today may be viewed in the Federal Register at <https://www.federalregister.gov/public-inspection>.