

»Business Alert

December 2009— Effects of the Health Information Technology for Economic and Clinical Health (“HITECH”) Act.

The Health Information Technology for Economic and Clinical Health (“HITECH”) Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (“ARRA”), was signed into law on February 17, 2009. The HITECH Act significantly expands the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and generally becomes effective February 17, 2010. Among the changes are the application of the privacy and security provisions and penalties to business associates of covered entities, new breach notification provisions, additional restrictions on certain disclosures and sales of health information, expansion of accounting requirements of certain protected health information disclosures and access to certain information in electronic format, additional restrictions on marketing and fundraising, and increased civil and criminal penalties for violations. This article summarizes these changes and their impact on health care entities.



Application of Privacy and Security Provisions and Penalties to Business Associates

Prior to the HITECH Act, business associates were not directly regulated by HIPAA, although they could be liable to covered entities for violation of security and privacy obligations under their business associate agreements with covered entities.

Business associates generally include persons or organizations that perform a function or activity on behalf of a covered entity or provide certain legal, financial, or management services to the covered entity that involves the use or disclosure of individually identifiable health information. Effective February 17, 2010, HIPAA’s privacy and security rules and penalties extend directly to business associates. The HITECH Act requires business associates to comply with HIPAA’s security provisions regarding implementation of administrative, physical, and technical safeguards as well as security policies, procedures, and documentation standards. The HITECH Act also requires business associates to comply with privacy provisions in their business associate agreements for the use or disclosure of protected health information (“PHI”) and take action if they know of a pattern of activity or practice by a covered entity that breaches their business associate agreements. Business associates are directly liable and subject to civil and criminal penalties for violations of the privacy and security provisions.

New Breach Notification Provisions

Prior to the HITECH Act, covered entities and business associates were not required to provide notification of a privacy or security breach. The HITECH Act mandates new breach notification obligations of covered entities and business associates. Covered entities are required to notify affected individuals of a breach of unsecured protected health information. In cases where a breach affects more than 500 individuals, the Department of Health and Human Services (“HHS”) and the media must be notified. Breaches affecting fewer than 500 individuals must be reported to HHS on an annual basis. Business associates of covered entities are required to notify the covered entity of any breaches under their control. HHS interim final regulations to implement this became effective on September 23, 2009. The ARRA requires similar obligations for vendors of personal health records and other non-HIPAA covered entities. The Federal Trade Commission (“FTC”) interim final regulations for vendors of personal health records and entities that contract with vendors became effective on September 24, 2009. HHS and FTC will not impose sanctions for the first 180 days following publication of the regulations.

Additional Restrictions on Certain Disclosures and Sales of Health Information

· The HITECH Act includes new restrictions on disclosures to health plans. Effective February 17, 2010, covered entities must comply with an individual's request not to disclose PHI to a health plan if the individual fully pays for the item or service.

The HITECH Act also clarifies the minimum necessary standards. Prior to the HITECH Act, a covered entity must generally make reasonable efforts to limit disclosure of PHI to the "minimum necessary" to accomplish the intended purpose, but does not define "minimum necessary". The HITECH Act requires HHS to publish guidance on what constitutes "minimum necessary", which should be available in the middle of next year. Effective February 17, 2010, and until the effective date of this guidance, covered entities must limit disclosure of PHI to a "limited data set" or, if needed, to the "minimum necessary" to accomplish the intended purpose.

In addition, the HITECH Act revises the prohibitions on sale of electronic health records or PHI. Except in certain specified situations, covered entities and business associates are prohibited from selling PHI without the individual's authorization. Regulations should be available in the middle of next year implementing this prohibition and will be effective six months thereafter.

Expansion of Accounting Requirements of Certain Protected Health Information Disclosures and Access to Certain Information in Electronic Format

· Prior to the HITECH Act, individuals generally have the right to receive an accounting of PHI disclosures by a covered entity made within the past six years. Covered entities were not required to account for disclosures to carry out treatment, payment, and health care operations. The HITECH Act expands the accounting requirements to disclosures of PHI maintained in an electronic health record by covered entities and business associates for treatment, payment, and health care operations made within the past three years. The effective dates for compliance vary depending upon when the covered entity or business associate receives the electronic health record.

In addition, effective February 17, 2010, individuals have the right to receive an electronic copy of PHI maintained in an electronic health record from covered entities. This information may be sent to the individual or another entity or person designated by the individual.

Additional Restrictions on Marketing and Fundraising

· Prior to the HITECH Act, covered entities and business associates can provide certain communications that might otherwise be considered marketing without individual authorization. Effective February 17, 2010, these communications will be prohibited if the covered entity receives remuneration unless the communication describes only a drug or biologic currently prescribed for the recipient and payment received by the covered entity is reasonable, the communication is made by the covered entity with a valid authorization, or the communication is made by a business associate on behalf of the covered entity and the communication is consistent with the written contract between the business associate and covered entity. The HITECH Act also places additional restrictions on fundraising communications and requires that recipients have the opportunity to opt out from receiving further communications.

Increased Civil and Criminal Penalties for Violations

· Prior to the HITECH Act, the maximum civil penalty was \$100 per violation and up to \$25,000 for all violations of an identical requirement or prohibition during a calendar year. Effective February 18, 2009, the HITECH Act increases the civil penalties for violations and creates tiered penalties for violations based on conduct, from \$100 per violation with a maximum of \$25,000 per year to a maximum of \$50,000 per violation with a maximum of \$1,500,000 per year. The enforcement interim final rule was issued by HHS in October 2009 and became effective on November 30, 2009.

This alert was authored by Tiffany Dou, an associate whose practice focuses on business, corporate and transactional matters. Ms. Dou represents and advises health care industry clients on a wide range of legal issues. For more information, contact Ms. Dou by sending a message to: Tiffany.Dou@GreshamSavage.com or calling (909) 890-4499.

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