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New HIPAA Requirements Included in the Stimulus Bill

Included in the recent American Recovery and Reinvestment Act of 2009, (the "Stimulus Bill") was the "Health Information Technology for Economic and Clinical Health Act" (or "HITECH Act"). The HITECH Act contains, among other things, new requirements under the HIPAA Privacy and Security Rules that effect health care providers, health insurance companies, and billing entities ("Covered Entities"), as well as "Business Associates." The new rules also effect vendors of electronic health record systems, information exchanges, and related services ("Vendors"). The effective date for many of the provisions will be 12 months from the date of enactment; however, other effective dates will be determined by the Secretary of Health and Human Services ("HHS")

The new requirements include very specific provisions for Covered Entities, Business Associates, and Vendors to report breaches of unsecured data containing individually identifiable, protected health information ("PHI"). Notification must be given to individual(s) whose PHI was breached, to HHS and to other government agencies. Public notification is also required where the PHI of more than 500 individuals is breached in a single event and HHS will post the information about such a breach on its website. Business Associates and Vendors in possession of PHI that is breached must also notify the Covered Entity that provided the PHI.

The HITECH Act also addresses the individual's right to request restrictions on disclosure of his or her PHI. Covered Entities using electronic health records ("EHRs") will now be required to account for disclosures of PHI for treatment, payment, and healthcare operations. For disclosures by a Business Associate, the Covered Entity may provide the accounting or may direct the individual to its Business Associates, who must comply with the accounting requirements. Such accountings are limited to the previous three years.

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<http://www.kgrlaw.com>

mjc@kgrlaw.com

lmb@kgrlaw.com

Among other highlights:

- Business Associates and Vendors must comply with many of the same formal program and technical information safeguards under HIPAA as required for Covered Entities and will also subject Business Associates to civil and criminal penalties for violations;
- A Covered Entity or a Business Associate cannot “directly or indirectly” receive remuneration in exchange for PHI of an individual, with certain exceptions related to copying fees and administrative costs for disclosures provided under a valid authorization; and
- Covered Entities with EHRs must provide an individual’s information in electronic form and transmit it to third parties, on the individual’s request.

The HIPAA healthcare operations exception for “marketing” has also been modified. Communications that were previously considered marketing are no longer treated as part of healthcare operations, and may require prior written authorization from the individual in order to contact him or her, subject to certain limited exceptions. Individuals must also be given a right to opt-out of receipt of a Covered Entity’s fund raising communications.

Finally, the HITECH Act includes a new tiered system of enforcement and penalties. Monetary penalties will be imposed after taking into consideration the scope of the offense, the ability to mitigate damages, and the existence of repeat offenses. Penalties for individual violations can be as high as \$50,000 with an annual cap of \$1,500,000 for identical violations occurring in the same year. In addition, HHS will now be required to formally investigate any complaint of a violation if a preliminary investigation of the facts in the complaint indicate a possible violation due to “willful neglect.” Violations deemed to result from willful neglect carry higher penalties.

For more information on the HIPAA Privacy Rules please contact Linda Batten at lmb@kgrlaw.com or Mark Colucci at mjc@kgrlaw.com.

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Contact Us

<http://www.kgrlaw.com>

mjc@kgrlaw.com

lmb@kgrlaw.com

Court Ruling Emphasizes Need to Update Services Agreements

A recent court ruling serves as a reminder that services agreements should be properly updated in writing as the conditions of the contract change. Last month a federal Court ruled in favor of a whistleblower who claimed that the exclusive contract between Carlisle Hospital and Health Systems (the "Hospital") and an anesthesiology group (the "Group") violated both the Stark Act and Anti-Kickback Act.

The Stark law restricts physician referrals for certain designated health services to any entity in which the physician has a financial relationship. The Anti-Kickback law prohibits the inducement of referrals for remuneration. Both laws are subject to certain "safe harbor" exceptions.

The complaint arose from the Group's agreement to provide 24/7 anesthesiology and pain management services at the Hospital (the "Agreement"). The Group was not charged for the space, equipment, and supplies necessary to provide such services. Several years after entering into the Agreement, the Hospital established a stand alone ambulatory surgical center and pain clinic ("Pain Clinic"). The Group provided services to the Pain Clinic pursuant to the Agreement, though the Agreement was never specifically amended to include Group services at the Pain Clinic.

The Court held that the Pain Clinic arrangement did not meet the safe harbor for "personal services arrangements" under Stark (and largely identical safe harbor under the Anti-Kickback statute) and violated Stark and Anti-kickback prohibitions on referrals. The Court reasoned that the safe harbor for personal services arrangements required a written contract and, because the Agreement was not amended to include the Pain Clinic, no written contract effectively existed for Pain Clinic services. The Court further reasoned that the Agreement, executed six years before the pain Clinic was established, could not accurately reflect the fair market value of the consideration given so far in the future and for a different type of facility. Therefore, the requirement that consideration be fair market value was not met.

This opinion emphasizes that arrangements between hospitals and physicians should be well documented and consistently updated to reflect changes in circumstances, such as new facilities. It also illustrates the high standard of compliance with Stark and Anti-Kickback laws to which health care providers are held.

For more information please contact Mark Colucci at mcj@kgrlaw.com or

Health Line



Contact Us

<http://www.kgrlaw.com>

mjc@kgrlaw.com

lmb@kgrlaw.com

Linda Batten at lmb@kgrlaw.com.

Perils and Pitfalls in Patient Billing Practices

There is a growing spotlight on billing practices in the health care industry. The area is likely to see significant action in the courts and legislature in the very near future.

Health care providers are increasingly concerned over billing for that portion of a bill that is the responsibility of a patient or otherwise unpaid by a third party payer. In a time of tight budgets, collections are more and more important but they can be difficult when the provider is out-of-network. If the patient is unwilling or to unable to pay, sending the claim to collections can be costly. Of course, there is also the risk that a patient will choose not to use the provider again because of "excessive" out-of network fees.

Low reimbursement rates also serve to pressure providers to "balance bill" patients. The New York Attorney General recently investigated, and in some cases filed suit against, several health plans, including Cigna and Wellpoint, for their use of Ingenix, a database used by the insurers that provided inaccurate rates and intentionally skewed "usual and customary" rates downward through faulty data collection and poor pooling procedures. Likewise, the AMA, along with several state medical associations and a group of individual physicians, filed separate class action lawsuits against Aetna Health, Inc. and CIGNA Corporation alleging those companies relied on the data provided by Ingenix to set unfair reimbursement rates for out-of-network care.

Given the pressures to balance bill patients, the practice is naturally gaining the attention of the courts. Last month, the California Supreme Court issued a unanimous decision in *Prospect Medical Group Inc. v. Northridge Emergency Medical Group* in which it addressed balance billing of HMO patients by providers of emergency services where the provider and HMO had no express agreement for payment. The Court held that balance billing by non-contracted emergency room providers was barred by California statute, though that statute did not specifically prohibit providers from balance billing the patients. The statute merely provided for a dispute resolution process between payers and providers when billing issues arose between non-contracting doctors and the payer. The Court liberally construed the statute to "suggest that doctors may not bill patients directly when a dispute arises between doctors and HMO's" but instead may only seek relief through the dispute resolution process. While the *Prospect* holding is binding only in California, it is indicative of a growing pattern of how States address balance billing and is

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Contact Us

<http://www.kgrlaw.com>

mjc@kgrlaw.com

lmb@kgrlaw.com

persuasive authority for other States that may soon consider the issue.

Not all forms of balance billing are prohibited. Providers may typically bill the patient for co-payments and out-of-pocket amounts that the insurer determines is the patient responsibility. Such payments are incentives to keep health care costs down.

Ironically, providers are also facing competing pressure to practice the opposite of balance billing: waiving co-pays and out-of-pocket payments. If providers choose not collect the co-pay or out-of-pocket amount from patients, they frustrate the contractual relationship between the patient and the insurer. The patient also may not meet his required deductible amount and may over utilize health care services. This, in the long run, can drive up insurance premiums for everyone.

Other problems also arise when providers *routinely* waive the out-of-pocket costs. Such waivers permit the provider to profit from the insurance payment while attracting more patients who enjoy such waivers. However, anti-kickback laws that prohibit inducement of Medicare referrals may be violated if the patients attracted are Medicare patients. Moreover, unfair competition claims by other providers may arise, creating animosity amongst providers and perhaps legal action.

Perhaps a larger concern is that routinely waiving co-payment obligations could lower the usual and customary rate that is normally considered the rate the provider actually collects from a claim. Some critics of the practice have indicated that if a provider routinely intends to only collect the amount paid by the insurer, then that amount becomes his usual and customary fee. An amount charged at a higher rate could actually be considered fraudulent.

The Centers for Medicare and Medicaid Services ("CMS") has stated that discounting uninsured and underinsured patients is acceptable. However, CMS has stressed that any discount policy should be set out in writing and should not be included in any advertising. Medicare and Medicaid co-payments can be discounted or waived, but only in cases of financial need.

While Indiana has not established strict prohibitions on balance billing or waiving patient out-of-pocket charges, the *Prospect* case should give one pause. Either practice could be prohibited with the stroke of a judge's pen. Of course, neither practice is without its pitfalls. In any event, billing practices and discounting policies should be put into writing and extreme care should be taken that they comply

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with Anti-kickback laws, Medicare regulations, and antitrust laws.

For more information on the anti-kickback statute or the Stark laws, please contact Linda Batten at imb@kgrlaw.com or Mark Colucci at mjc@kgrlaw.com.
