

Health Law ADVISORY

Current legal insights for health care executives

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Julie A. Knutson, Editor

HHS Issues Interim Final Rule On HITECH'S Breach Notification Requirements

On August 24, 2009, the Secretary of the Department of Health and Human Services (HHS) issued an Interim Final Rule (the Rule) on breach notification requirements for covered entities and their business associates, pursuant to Section 13402 of the Health Information Technology for Economic and Clinical Health Act (HITECH), which was passed earlier this year as part of the American Recovery and Reinvestment Act of 2009. HITECH and the Rule require covered entities and business associates to make major additions to their HIPAA privacy and security policies.

In general, the breach notification component of HITECH requires covered entities and their business associates who experience a Breach of Unsecured Protected Health Information (or Unsecured PHI) to send notifications to individuals affected by the Breach. The Rule provides specific definitions of the terms "Breach" and "Unsecured PHI," including exceptions to the definition of Breach, and specific notification rules that covered entities and business associates must follow. It is important to keep in mind that the data breach notification requirements apply to *paper* and *verbal* breaches to the same extent as to security incidents involving an electronic medical record.

Because HITECH's breach notification requirements apply only in the case of a Breach, having a clear understanding of the meaning of Breach is crucial. In general, the Rule defines Breach as the acquisition, access, use or disclosure of protected health information in a manner not permitted under the HIPAA Privacy Rule, which poses a significant risk of financial, reputational, or other harm to the individual whose information was acquired, accessed or used. However, the definition excludes the following occurrences:

- an unintentional acquisition, access, or use of protected health information by a person acting under the authority of a covered entity or business associate, as long as such acquisition, access, or use was made in good faith and within the scope of such authority, and does not result in further use or disclosure of the information;
- an inadvertent disclosure by a person authorized to access protected health information at a covered entity or business associate to another authorized person at the same covered entity or business associate (or an organized health care arrangement in which the covered entity participates), which does not result in a further disclosure of the information; and

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- a disclosure of protected health information where the covered entity or business associate has a good faith belief that the person to whom the information was disclosed would not reasonably have been able to retain the information.

These exceptions will be difficult to apply in many cases. In addition, the Rule requires the covered entity to conduct a risk analysis to evaluate whether there is potential for significant risk of financial, reputational or other harm to the individual. Applying the exceptions and conducting the risk analysis will present new challenges for covered entities.

The obligation to report a Breach only arises if the Breach involves Unsecured PHI. The Rule defines “Unsecured PHI” as protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by HHS in the Rule and other guidance. The only approved methods of securing PHI are *encryption* and *destruction*.

For the instances in which a true Breach of Unsecured PHI has occurred, the Rule provides specific instructions with respect to whom covered entities and their business associates must provide notice, the required contents of such notifications, and when and by what means such notifications must be made. In general, a covered entity must provide written notice to each individual whose Unsecured PHI is reasonably believed by the covered entity to have been disclosed in the Breach, without unreasonable delay and in no case later than 60 days after discovery of the Breach. If the Breach involved the Unsecured PHI of more than 500 total individuals, notification also must be made to the Secretary of HHS; in cases of Breaches affecting fewer than 500 individuals, covered entities must provide the Secretary with a Breach log on an annual basis. Furthermore, if the Breach involved the Unsecured PHI of more than

500 individuals of a single state, notice also must be made to prominent media outlets in that state. Finally, if a business associate of a covered entity discovers a Breach, it has a duty under the Rule to notify the covered entity of such Breach.

Subject to changes based on comments received by the Secretary, the Rule and its requirements become effective and apply to Breaches that occur on or after **September 23, 2009**.

Vickie B. Ahlers

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Iowa Hospital Settles Excessive Physician Compensation Claims

On August 25, 2009, the Department of Justice announced that it settled with Covenant Medical Center in Waterloo, Iowa for \$4.5 million to resolve allegations that Covenant paid excessive compensation to five employed physicians in violation of Stark.

This settlement relates back to a matter first raised in the summer of 2005 by a competing private medical group in Waterloo, in which the CEO of the group contended that Covenant’s payments to its physicians constituted “excessive and

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unfair competition” and that his physicians work just as hard for 1/3 the compensation. The Covenant CEO responded that there was no basis to compare with unreported earnings of others, that the physicians work hard – top 1% nationally, that compensation was calculated based on collections less business expenses, and that Covenant’s tax status did not add to their income. The medical group sued in state court alleging a civil conspiracy to monopolize health care and misuse of tax-exempt status to pay physicians excessive salaries to drive the medical group out of business. The claims were dismissed. Subsequently, it was reported that the OIG had subpoenaed claims records from the primary commercial carriers in the area concerning the amounts paid by those carriers to Covenant physicians.

The Department of Justice states in its press release that

“This settlement resolves allegations that Covenant submitted false claims to Medicare by having financial relationships with five physicians that violated the Stark Law. The Stark Law prohibits a hospital from profiting from referrals of patients made by a physician with whom the hospital has an improper compensation arrangement. An arrangement is improper if a physician is paid above fair market value for their services and that compensation is not commercially reasonable. The Stark Law is intended to ensure that physicians’ medical judgments are not compromised by improper financial incentives and are based solely on the best interests of the patient.

The United States alleged that Covenant violated the Stark Law by paying commercially unreasonable compensation, far above fair market value, to five employed physicians who referred their patients to Covenant for treatment. These physicians were among the highest paid hospital-employed physicians not just in Iowa, but in the entire United States.”

Covenant reported that the hospital’s highest-paid physician, a gastroenterologist, was part of the inquiry and was paid \$1.8 million in 2008. The other four physicians that allegedly received excessive compensation have not been identified but a Covenant spokesman has reportedly confirmed that the five doctors in question are two orthopedic surgeons, two neurosurgeons and a gastroenterologist. However, the 2005 news reports about this matter stated that Covenant’s 2002 physician compensation included \$2.1 million to an employed orthopedic surgeon, \$2.1 million to an employed gastroenterologist; and \$1 million to an employed orthopedic surgeon.

This settlement is one of the first of which we are aware in which the Government has alleged excessive compensation paid to hospital-employed physicians. The lack of further information about the basis for the allegations of the DOJ and OIG limits the precedential or educational value of this settlement, but it reinforces that the hospital-physician integration strategy of employing physicians, while generally viewed as a safer strategy from a compliance perspective, still requires careful attention to compliance.

Hospitals should adopt compliance strategies to include a board adopted policy for setting and review of employed physician compensation and methodology, regular review and documentation of the reasonableness of such compensation, and a process for board review of compensation of physicians above certain comparative thresholds.

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John R. Holdenried

Recent Immigration Developments

There have been a number of developments in federal and state immigration law that are of interest to health care employers:

USCIS Extends Validity of Form I-9

On August 27, the United States Citizenship and Immigration Service (USCIS) announced the issuance of a new version of Form I-9, Employment Eligibility Verification Form, which will be valid through August 31, 2012. No substantive changes have been made to the Form I-9; employers may use either the current version dated 08/07/09, or the prior version dated 02/02/09 (in the bottom right corner). The February version of the Form has been required for use by all employers since April 3, 2009. If you are not yet using either version of Form I-9, you should begin to do so as soon as possible and will need to correct any forms completed on or after April 3, 2009.

The USCIS issued a new *Handbook for Employers*, designed to reflect the new regulations issued in 2008 and applicable to Form I-9 compliance for all employers. One fairly significant change is that employers may no longer present expired identification documents for employment verification. (See [December 2008's Labor and Employment Law Update](#) for details.)

Failure to use the current Form I-9 or comply with new regulations governing completion of the Form may result in administrative penalties and fines. You can access a copy of the Form and the *Handbook* on the USCIS web site at www.uscis.gov.

2010 H-1B Quota Remains Available

For each fiscal year, federal law imposes a cap on the number of H-1B visas available to U.S. employers. Under current law, the available quota is limited to 65,000, with a separate quota of 20,000 visas for certain “advanced degree” situations. Unlike recent years, H-1B visas remain available for employers for the 2010 fiscal year. If you have a candidate in need of such a visa, a petition for an H-1B visa may be filed now for employment start dates beginning on October 1, 2009. If an earlier start date is needed, many hospitals qualify as a cap-exempt employer through affiliations with institutions of higher education. Also, some individuals are exempt as current visa recipients or as recipients of certain J-1 waivers.

Department of Homeland Security Changes Enforcement Focus to Employers

U.S. Immigration and Customs Enforcement (ICE) recently announced that it issued 654 Notices of Inspection (NOIs) to businesses suspected of employing illegal workers. In one day, ICE issued more notices than were issued during all of the prior fiscal year. The new head of ICE confirmed this month that his agency will intensify its crackdowns on employers and is set to increase further the number of companies it will audit and fine. The notices come as part of a new ICE initiative to hold employers accountable for maintaining a legal labor force announced by the Obama administration, which has clearly stated that its enforcement activities will be focused on employers, rather than the raid-focused enforcement endorsed by the prior administration.

The Form I-9 records of each of the businesses receiving an NOI will be audited by ICE to assure compliance with national employment eligibility verification laws and regulations. The consequences for offending businesses are high—penalties range from \$375 to \$16,000 per incident and can include up to 6 months in prison.

If ICE can show that supervisors or HR personnel know employees are working with fraudulent documents, this knowledge may be imputed to management with resulting corporate liability, including seizure of assets and criminal liability for top executives.

If ICE can show that supervisors or HR personnel know employees are working with fraudulent documents, this knowledge may be imputed to management with resulting corporate liability, including seizure of assets and criminal liability for top executives. Consequently, businesses are well advised to maintain accurate employment records. If audited, businesses are required to submit Form I-9s within 72 hours of notice, leaving little time to remedy deficiencies. All employers should conduct audits of their Form I-9s at least annually to ensure that Forms are being prepared timely and correctly.

Conrad Waiver Program for J Visa Physicians

All international medical graduates who enter the U.S. on a J visa to complete medical training are subject to a two-year foreign country residence requirement, which must be completed in the individual's home country, before the physician is eligible to be granted an H-1B visa for employment in the U.S. The State Conrad 30 J-1 Visa Waiver Program is a popular program through the states to act as an Interested Government Agency (IGA) and recommend a waiver to the U.S. Department of State of this requirement. Recently, Congress has extended this Program to September 30, 2012.

The Program requires that the physician have an employment offer that is important to the state's department of health and be willing to practice either primary care or specialty medicine, full-time for three years, in an area of the state designated by the U.S. Secretary of Health and Human Services as Health Professional Shortage Areas (HPSA) or Medically Underserved Area or Population (MUA/P). At this time, waivers remain available in some states, including Nebraska, for physicians completing medical training before October 1, 2009. The next group of waivers become available in all states beginning on that date.

Nebraska's LB 403: New Verification Requirements for Employers

LB 403 becomes effective October 2009. It requires verification of lawful presence in the United States for certain public benefits and verification of employment eligibility for certain "public" employers and certain tax incentive programs.

Under the new law, all public employers and all public contractors and/or their subcontractors must verify the employment authorization of all new employees. A public contractor is defined as "any contractor or his or her subcontractor who is awarded a contract by a public employer for the physical performance of services within the State of Nebraska." As a condition of contracting with a Nebraska public employer, contractors and subcontractors must verify the employment eligibility of all new employees physically providing services within the state through a federal immigration verification; and, any contract between a contractor and a public employer must include a provision requiring the contractor to do so. Currently, this would mandate the use of the E-Verify Program.

If you are a public employer, e.g., a county or city hospital, you will need to register with the Department of Homeland Security (DHS) and sign-up as an E-Verify employer before October. This process includes signing a Memorandum of Understanding with DHS and the Social Security Administration (SSA) that requires you to provide and post certain notices, allowing DHS and SSA to make periodic visits to review E-Verify-related records (including Form I-9s and other employment records) and interview employees, and reporting to DHS when the employer decides to employ someone despite a non-confirmation.

If you are a public employer, e.g., a county or city hospital, you will need to register with the Department of Homeland Security and sign-up as an E-Verify employer before October.

**Amy Erlbacher-Anderson
Labor, Employment and Employee
Benefits Section**

Wife of Owner of Rehabilitation Company Held Liable Under False Claims Act

In a recent federal court decision, the wife of the owner of a Michigan-based rehabilitation company was determined to be liable for \$876,548 under the False Claims Act (FCA) for signing incorrect cost reports and accepting payment for services that were not provided even though the defendant was not the preparer of the cost report.

The company in question was engaged in providing rehabilitation and pain management services to patients in Michigan. The defendant was accused of signing and certifying incorrect cost reports from 1995 through 1998 and accepting and endorsing checks from the government as payment for services she knowingly did not render. The cost reports in question included exhibits that listed the defendant, Mona Khan, as the Executive Director and manager of her husband's rehabilitation company. Those same cost reports listed the defendant's annual hours worked as 2340 and cited her duties as being the overall supervisor of fiscal and community relations and the day-to-day operational manager of the company. Each cost report listed the defendant's salary and benefits for the year as being \$342,341. The company also provided W-2's as support reflecting that this compensation was actually paid out each year. The defendant signed the

cost reports, each of which contained the typical certification language that all the statements therein were true and correct and that knowingly misrepresenting information on the cost report could lead to conviction and imprisonment and/or fines being assessed under federal law.

The court was also presented the testimony of the defendant's spouse that definitively established that the defendant did not and had not worked for the company as its executive director or in any other manner. Yet, the wife received and cashed paychecks from the company. The government submitted copies of cancelled checks that were allegedly endorsed by the defendant and proved, through the use of handwriting experts, that it was the defendant who endorsed the checks.

The court stated that the FCA imposes liability on any person who knowingly presents, or causes to be presented, to an officer or employee of the United States a false or fraudulent claim for payment. The government argued that the defendant violated this provision of the FCA by signing and presenting cost reports to the Medicare program for payment while knowing that the cost report contained materially false information relating to the defendant's employment. According to the court, the FCA does not require that the defendant be the party who actually prepared the cost report; it just requires that she sign the cost report while knowing that it contained false information. The argument that her husband was the guilty party because he prepared the fraudulent cost report and she only signed the cost report at his request was not successful. Furthermore, the court determined that the government need not prove that the defendant had actual knowledge that the cost report was false in order to prove liability under the FCA. While the court believed that the defendant more than likely knew that the cost report was false, it did not need to make such a finding. The court determined that when the defendant signed the cost report and endorsed the improperly paid checks, she was acting, at the very least, with reckless disregard, which satisfies

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the knowledge requirement under the FCA. The court found the defendant liable under the FCA and assessed treble damages in the amount of \$856,548.

This case serves as a reminder that parties who sign cost reports must have a good faith belief that everything in the cost report is truthful and accurate. Signing a cost report at the request of another without knowing the contents is unlikely to constitute a successful defense under the FCA.

Andrew D. Kloeckner

Free Blood Pressure Screens

The Office of Inspector General (OIG) recently issued Advisory Opinion 09-11 in which it addressed providing free blood pressure screenings to individuals who walk in to the hospital without a prior appointment. This Advisory Opinion is of great importance to those providers who regularly provide blood pressure screens and other comparable tests to individuals free of charge as it sets forth certain elements which the OIG believes are key to preventing the violation of § 231 of HIPAA and the federal anti-kickback statute.

In the Advisory Opinion, the requestor was a small public critical access hospital that provided routine blood pressure screenings free of charge to anyone who came to the hospital and requested a screening. The hospital did not advertise blood pressure screens, and the visitor was not required to purchase any additional goods or services

from the hospital. Furthermore, the individuals receiving the free screens were not offered any other discounts on any other hospital services, such as follow-up visits. If the results of a screen fell outside of an acceptable range, the individual was directed to see his or her personal physician unless the test concluded that an emergency existed. In such a case, the individual would be directed to the hospital's emergency room. The hospital did not bill Medicare, Medicaid or any other program for the provision of the screen.

The OIG has provided guidance suggesting that items of nominal value (\$10 per item or \$50 in annual aggregate) provided to program beneficiaries will not constitute remuneration under HIPAA or the anti-kickback statute. However, in this case, the OIG noted that, because there was no limit on the number of times an individual could receive a free blood pressure screen, the previous guidance did not apply. Instead, the OIG held that the blood pressure screens satisfied the preventive care exception. Under that exception, the OIG analyzed the arrangement to determine whether the free care would promote the provision of other non-preventive care reimbursable by Medicare and Medicaid. It concluded that the free blood pressure screens were unlikely to result in the provision of additional reimbursable services, citing a similar permitted hypothetical arrangement discussed in the Preamble to the final rule on the CMP relating to free blood pressure screenings.

This Advisory Opinion confirms that the OIG believes free services provided to program beneficiaries implicate both the civil monetary penalty provisions of § 231 of HIPAA and the federal anti-kickback statute, especially when the hospital does not limit the free tests to the \$10 per item or service and \$50 annual aggregate amount. However, it found that the provision of such blood pressure screenings would not constitute grounds for the imposition of civil monetary penalties under § 231 of HIPAA and would not result in civil monetary penalties

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or administrative sanctions under the federal anti-kickback statute because of the protections the hospital put in place to ensure that the program would not lead to the purchase of additional items or services billable to the Medicare or Medicaid program. Thus, when providing free blood pressure screens or other tests, a hospital should be sure to observe the safeguards cited by the OIG in the Advisory Opinion. Specifically, a hospital *should not*:

- Advertise free screenings.
- Require recipients to purchase any additional goods or services from the hospital.
- Offer any discounts on follow-up items or services.
- Direct patients to receive follow-up care at the hospital unless the test results rise to the level of an emergency. Unless an emergency exists, the individual should be directed to see his or her own personal physician for follow-up care.
- Bill Medicare, Medicaid or any other third party payor for the provision of the screen.

Andrew D. Kloeckner

Michael Chase Joins Health Law Section

Michael Chase will join the Health Law Section as an associate attorney on September 8, 2009. Michael is a 2009 joint-degree graduate of St. Louis

University's School of Public Health and School of Law, receiving both a Master of Health Administration and a law degree with a certificate in health law. While in school, Michael served as a staff editor for *The Journal of Health Law and Policy*, and completed an administrative internship in the Department of Surgery at Mayo Clinic in Rochester, Minnesota.

Upcoming Speaking Engagements:

Julie Knutson will speak on "Documentation and Medical Necessity," on Thursday, September 17, 2009, as part of the Nebraska Rural Health Association's Certified Rural Health Clinics Coding and Billing Workshop in Kearney, Nebraska. Registration information available from mbeaudette@mwhc-inc.com.

Kelly Clarke will participate in a panel discussion of "Legal and Regulatory Considerations in Handling Disruptive Physicians" on October 8, 2009 at the Iowa Hospital Association Annual Meeting in Des Moines.

Save the Date!

The 21st Annual Health Law Forum will be held on Friday, November 20, 2009 at the Marriott Regency in Omaha, Nebraska.

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