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HALL RENDER'S

PRACTICALHEALTH:.

A Brief Overview of the Major Health Reform Provisions Affecting Health Care Providers Beginning in 2010

The Health Reform Act provides for a progressive phase-in of its provisions from 2010 through 2018 with the most significant changes affecting hospitals and other providers set for 2014.

The Patient Protection and Affordable Care Act (the "Act") was signed by President Obama on March 23, 2010. On March 30, 2010, President Obama signed into law the Health Care and Education Reconciliation Act of 2010 (the "Reconciliation Act"), which includes a number of budget-based corrections to the Act. Both the Act and the Reconciliation Act (together the "Health Reform Act") constitute a complex, intricate piece of health reform legislation. This article lists some of the major provisions of the Health Reform Act affecting hospitals and other health care providers that are scheduled to go into effect beginning in 2010. Most of the measures made effective in 2010 have a relatively limited direct effect on health care providers such as hospitals. The Health Reform Act provides for a progressive phase-in of its provisions from 2010 through 2018 with the most significant changes affecting hospitals and other providers set for 2014, when individuals are required to purchase health insurance and the insurance exchanges are up and running.

SECTION 501(C)(3) CHARITABLE HOSPITALS - ADDITIONAL REQUIREMENTS.

Section 9007 of the Act amends Section 501 of the Internal Revenue Code of 1986 to require tax-exempt 501(c)(3) hospitals, every three years, to conduct a "community health needs assessment" that takes into account input from individuals in the hospital community, including those with special knowledge or expertise in public health. The hospital must adopt an implementation strategy to meet the community needs identified by the assessment. Further, the tax-exempt hospital must put into place the following policies:

- Financial Policies that address eligibility criteria for financial assistance including free or discounted care, the basis for calculating amounts charged to patients, the method for applying for financial assistance, and the collection and credit agency reporting actions the hospital may take, if the hospital does not have a separate billing and collections policy; and CONTINUED ON PAGE 2

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HHS POSTS LISTING OF UNSECURED PHI BREACHES

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' ("HHS") CIVIL RIGHTS OFFICE POSTED A LIST OF UNSECURED PROTECTED HEALTH INFORMATION BREACHES ON ITS WEBSITE ON FEBRUARY 22, 2010. The posting includes brief descriptions of the breaches reported by covered entities or covered entities' business associates pursuant to the American Recovery and Reinvestment Act of 2009 ("ARRA"). Covered entities and business associates must notify HHS upon a breach of unsecured protected health information ("PHI") that compromises the security or privacy of the PHI. Covered entities must tell HHS within 60 days of the breach of PHI affecting more than 500 individuals, and HHS then posts a description of the breach on its website. The current list includes breaches reported by over 35 sources, including private medical practices, health insurance companies, hospitals, universities, health care systems and public agencies. The majority of breaches resulted from theft of computers, hard drives, portable electronic devices, backup tapes and paper records. The number of individuals affected by the breaches ranged from 501 individuals to as many as 500,000 individuals.

The posted breaches are available at: http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/postedbreaches.html ■

Major Health Reform Provisions (Continued)

- An Emergency Medical Care Policy making it clear that the hospital is obligated to provide care for emergency medical conditions regardless of a patient's eligibility for financial assistance.

Under Section 9007, tax-exempt hospitals are prohibited from charging patients, who are eligible for financial assistance, more than the lowest amounts billed to insured patients for emergency and other medically necessary care, and must not engage in "extraordinary collection actions" prior to making a "reasonable effort" to determine whether a patient is eligible for financial assistance under the hospital's policy. The Health Reform Act authorizes the promulgation of implementing regulations and guidance to carry out these additional requirements for 501(c)(3) hospitals, and any hospital not complying is subject to an excise tax of $50,000. Further guidance will be necessary to define what constitutes "extraordinary collections actions" and "reasonable efforts" to determine eligibility for financial assistance in this context.

RURAL HOSPITALS.

The Act extends Medicare payment protections for small rural hospitals that play a crucial role in providing care in underserved communities. For example, Section 3122 of the Act provides for the extension of Medicare "reasonable cost payments" for clinical diagnostic lab services provided in rural hospitals.

PROVIDER SCREENING.

Section 6401 of the Act and Section 1304 of the Reconciliation Act provide for federal health care program provider/supplier screening and enhanced oversight for new providers and suppliers to aid in the government's efforts to reduce fraud and abuse. Screening must include licensure checks and may include criminal background checks, fingerprinting, and unscheduled and unannounced site visits. Fees are assessed for such screenings and effective dates vary depending on the status of the provider/supplier. The Secretary of HHS may impose a temporary moratorium on the enrollment of new providers and suppliers if the Secretary determines the moratorium is necessary to combat fraud and abuse. CONTINUED ON PAGE 3

ENHANCING PRIMARY CARE.

Section 10503 of the Act provides funding to construct new, and expand existing community health centers. The Act also provides for increased funding for scholarships and loan repayments for primary care practitioners working in underserved areas.

PHYSICIAN SELF-REFERRAL LIMITATIONS.

Section 6001 severely restricts physician ownership in hospitals under the Stark Law "whole hospital exception," effectively prohibiting future investment in new hospitals and limiting the expansion of existing hospitals. Section 6003 of the Act amends the "in-office ancillary services exception" under the Stark Law to require a physician to disclose to patients that they may receive MRI, CT and PET imaging services provided by the physician from other local providers and, further, to require the physician to furnish a list of alternate providers in the patient's local area.

DRUG MANUFACTURERS.

The Act authorizes the FDA to grant biologic drug manufacturers twelve years of exclusive use before generic manufacturers can develop generic versions.

Implementation timelines for subsequent years and in-depth analyses on the provisions introduced above as they affect the various stakeholders will be forthcoming in future Health Law Broadcasts .

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HITECH: When is a PHI Breach Notification Required?

February 17, 2010 marked the one year anniversary of the date President Obama signed the American Recovery and Reinvestment Act of 2009 ("ARRA") into law. As part of ARRA, the Health Information Technology for Economic and Clinical Health ("HITECH") Act was enacted to increase hospital and physician use of electronic health records. On August 24, 2009, the Department of Health and Human Services ("HHS") published its interim final rule regarding breach notification requirements applicable to covered entities and their business associates under HIPAA (the "Rule"), as required by Section 13402 of HITECH. The Rule, effective September 23, 2009, requires covered entities to notify affected individuals and HHS in the event of a breach of unsecured protected health information ("PHI") that compromises the security or privacy of such PHI. As of February 22, 2010, failure to make such disclosures may result in the imposition of sanctions by HHS.

DID A BREACH OCCUR?

The Rule defines a "breach" as the "unauthorized acquisition, access, use, or disclosure of PHI in a manner not permitted [by the HIPAA Privacy Rule] which compromises the security or privacy of the PHI." The Rule provides the terms "acquisition" and "access" are encompassed within the current definitions of the terms "use" and "disclosure" under the Privacy Rule.

The Rule states a violation "compromises the security or privacy of PHI" if the breach "poses a significant risk of financial, reputational, or other harm to the individual." This element of the definition requires covered entities and business associates to perform a risk assessment. In doing so, a covered entity should consider: (i) who used or to whom was the PHI disclosed; (ii) what steps were taken to mitigate the use or disclosure; (iii) what type and amount of PHI was involved; and (iv) whether the use or disclosure involved sensitive information.

If the risk assessment indicates a violation of the Privacy Rule does not pose a significant risk to the individual, then no notification is required. A wrongful use or disclosure of PHI would not be considered a breach if the PHI at issue was only a "limited data set" (no direct identifiers) and did not include dates of birth or zip codes.

WAS THE PHI UNSECURED?

Unsecured PHI is PHI not rendered unusable, unreadable or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary of HHS. The PHI will be deemed "unsecured" if it is not secured by:

- Encryption of electronic data per National Institute Standards and Technology ("NIST") standards;
- Destruction of electronic media per NIST standards; or
- Shredding or destruction of paper, film or other hard copy media.

DOES AN EXCEPTION APPLY?

The Rule clarified and reiterated the three exceptions under Section 13400(1) of HITECH, which include: CONTINUED ON PAGE 4

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With more than 140 attorneys, Hall Render partners with clients to direct them through the ever-changing business landscape of today's health care industry. Health care is our business.

When is a PHI Breach Notification Required? (Continued)

- Unintentional acquisition, access, or use of PHI by a workforce member acting under the authority of a covered entity or business associate, if done in good faith and the information was not further used or disclosed;
- Inadvertent disclosure of PHI by a person authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the same covered entity, business associate, or organized health care arrangement, and the PHI was not further used or disclosed; and
- A disclosure of PHI where there is a good-faith belief by the covered entity or business associate that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

The covered entity or business associate has the burden of proof for showing an exception applies.

REQUIRED NOTIFICATIONS.

A covered entity must notify affected individuals and HHS for all breaches under the Rule. All notifications must be given to the affected individual without "unreasonable delay," but no later than 60 days after the first day the breach is known, or by reasonable diligence would have been known, to the covered entity. The Rule requires business associates to notify the covered entity under the same standard, but business associates are not required to provide the notifications themselves. Section 13402(f) of the Act sets forth the content requirements for the breach notice, which include: (i) a brief description of what happened; (ii) a description of the types of unsecured PHI involved; (iii) any steps individuals should take to protect themselves from potential harm; (iv) a brief description of what the covered entity is doing to resolve the issue; and (v) contact procedures for individuals to ask questions or learn additional information.

If a breach involves more than 500 individuals, HITECH requires covered entities to notify HHS without unreasonable delay as well as notify prominent media outlets. For breaches involving fewer than 500 individuals, a covered entity shall maintain a log of such breaches and annually submit such log to HHS documenting the breaches occurring during the year involved. The log must be submitted to HHS by March 1 of each year for breaches occurring during the previous calendar year.

The Rule is available at: http://edocket.access.gpo.gov/2009/pdf/E9-20169.pdf. ■

CONTRIBUTING AUTHORS

ATTORNEY ROBIN EBERT focuses her practice on health care law and corporate transactional law. She counsels clients on a variety of health care related issues, including hospital and physician joint ventures, fraud and abuse, the Stark law, regulatory and corporate compliance, physician contracting and tax exemption issues. Robin earned her law degree from Indiana University School of Law-Indianapolis in 2008 and completed the health law concentration with honors.

ATTORNEY JANE SUSOTT advises clients in numerous aspects of health care law, including hospital and physician arrangements; Fraud and Abuse/Stark issues; preparation and review of hospital, physician and other provider contracts; physician recruitment; corporate compliance issues; medical staff and peer review; accreditation matters; and Medicare reimbursement issues. Jane graduated cum laude from Indiana University School of Law-Bloomington in 2007.

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