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HEALTH CARE LAWYERS

HEALTH LAW PERSPECTIVES

Newsletter
Volume 15, No. 3 May 2013

HITECH Compliance Tune-Up

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The final rule implementing the privacy and security provisions of the HITECH Act issued in January of this year requires health care providers to revisit and in many cases revise their HIPAA policies before the rule's September 23, 2013 implementation deadline. The Centers for Medicare and Medicaid Services (CMS) has also established its expectation, at least for eligible professionals, that a security risk analysis needs to be performed or reviewed for each meaningful use reporting period. We believe this will also likely be applied to eligible hospitals as well.

As we advised in our March 11, 2013 client alert on modifying business associate agreements to comply with the final rule, the final rule sets a deadline of September 23, 2013 for updating business associate agreements. Business associate agreements entered into before January 25, 2013 do not need to be amended until September 22, 2014, unless they are modified earlier for other reasons – in which case the new changes must be incorporated.

As a practical matter, business associate agreements entered into after January 25, 2013, should comply with the new rule, even though it is not yet in effect. Otherwise, they will need to be amended by September 23, 2013.

In its commentary to the final rule, the Office for Civil Rights (OCR) indicated that the rule's revisions to existing HIPAA law will require covered entities to revise their notices of privacy practices. The basis for OCR's statement lies in the Privacy Rule at 45 CFR 164.530(i)(3), which provides: "Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by § 164.520 [the section mandating covered entities to provide notices privacy practices to patients], the covered entity must promptly make the appropriate revisions to the notice in accordance with § 164.520(b)(3)." That part of the Privacy Rule also provides: "The covered entity may not implement a change to the policy or procedure prior to the effective date of the revised notice." 45 CFR 164.520(b)(4)(i)(C).

OCR has essentially declared the final rule's revisions to necessitate changes to notices of privacy practices that are based on HIPAA's pre-HITECH provisions. Moreover, under the terms of the existing Privacy Rule, a covered entity cannot implement the final rule's provisions until the effective date of its revised notice of privacy practices.

Covered entities will therefore want with all due haste to review and revise as necessary their notices of privacy practices to address various aspects of

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the HITECH final rule as well as any other changes in their operations. The changes made by the HITECH final rule that may need be incorporated into a notice of privacy practices include:

- If a covered entity uses protected health information (PHI) for fundraising purposes, its notice of privacy practices must inform patients that they have the right to opt out of fundraising solicitations. Until the HITECH final rule goes into effect, a notice of privacy practices must only inform patients that they may be contacted for fundraising; the solicitation itself must tell the individual how to opt out, but the notice of privacy practices does not currently have to explain the opt-out right.

- The HITECH final rule requires that a notice of privacy practices inform patients of a covered entity's obligation to notify a patient following a breach of the patient's unsecured PHI.

- Currently, a notice of privacy practices must advise patients of their right to request restrictions on the use or disclosure of their PHI and include a statement that the covered entity is not required to comply with the request. After the HITECH final rule goes into effect, a covered entity must state that it is required to comply with a request not to disclose PHI to a health plan for payment or health care operations where the individual pays out-of-pocket for a service.

- If a covered entity intends to use or disclose psychotherapy notes in circumstances requiring authorization, use or disclose PHI for marketing, or sell PHI, the HITECH final rule requires that its notice of privacy practices inform patients that an authorization is required for these purposes.

As part of the meaningful use program, participating eligible professionals and eligible hospitals must attest to having conducted or reviewed a security risk analysis prior to or during the EHR reporting period. CMS has stated in its description of the security risk analysis core measure for eligible professionals that the security risk analysis may occur prior to the beginning of the first EHR reporting period, but that a new analysis or review of an existing one would have to occur for each subsequent reporting period. [The description for eligible professionals can be found online at this link: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/15_Core_ProtectElectronicHealthInformation.pdf] Because the same regulatory language is used for eligible hospitals, it is likely that CMS would require a new analysis or review for each subsequent reporting period for eligible hospitals as well. Many providers who have undergone EHR audits have been alleged to have not properly performed a security risk analysis as required under 45 CFR 164.308(a)(1). The failure to meet this core measure may result in a recoupment of EHR incentive payments

The Security Rule provides at 45 CFR 164.306(e) that: "Security measures implemented to comply with standards and implementation specifications adopted under § 164.105 and this subpart must be reviewed and modified as needed to continue provision of reasonable and appropriate protection of electronic health information as described at § 164.316." At 45 CFR 164.316(b)(2)(iii) the rule similarly states that a covered entity must "[r]eview documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information." The Privacy Rule has a parallel provision regarding policy and procedure updates at 45 CFR 164.530(i)(2)(i): "A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart or subpart D of this part."

In its July 14, 2010 "Guidance on Risk Analysis Requirements Under the HIPAA Security Rule," available at this link: http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidance.html, OCR stated:

The Security Rule does not specify how fre-

quently to perform risk analysis as part of a comprehensive risk management process. The frequency of performance will vary among covered entities. Some covered entities may perform these processes annually or as needed (e.g., bi-annual or every 3 years) depending on circumstances of their environment.

As noted above, for meaningful use participants, OCR appears to require that a risk analysis be conducted or reviewed annually to comply with the "as needed" language of Section 164.306(e). Because of the similar language regarding policies and procedures in Sections 164.316(b) and 164.530(i), we believe OCR may take the position that policies and procedures must be reviewed annually and revised if the review indicates changes are needed to accurately and completely reflect any changes in law, environmental or operational circumstances or technology.

Given what seems to be an almost annual revision of HIPAA through the issuance of regulatory changes, we believe covered entities and business associates should consider implementing annual reviews of HIPAA policies and risk assessments as a best practice. For example, in addition to this January's final rule, OCR will be issuing a rule implementing HITECH's provisions regarding accounting disclosures from an electronic health records as well as refinement of the minimum necessary standard. Prior years have seen other changes to either the Privacy Rule or the Security Rule.

Hooper, Lundy & Bookman assists clients with a range of HIPAA compliance activities, including the drafting and revision of policies and procedures, guidance on the legal standards for conducting risk assessments and implementing other HIPAA implementation standards and safeguards, workforce training and managing data breaches.

For more information or assistance, please contact: In San Francisco, Steve Phillips, Paul Smith, Clark Stanton, or Felicia Sze at 415.875.8500; in Los Angeles, Hope Levy-Biehl, Karl Schmitz or Amy Joseph at 310.551.8111; in San Diego, Jennifer Hansen at 619.744.7300; and in Washington, D.C., Robert Roth at 202.580.7700.

Federal Appeals Court Rules in Favor of Hospitals Seeking GME Data Correction for Closed Cost Reports

In a decision potentially worth tens of millions of dollars for 10 Southern California Kaiser Foundation teaching hospitals, the Washington, D.C. federal Court of Appeals has affirmed a lower court ruling favoring Kaiser in a case involving Graduate Medical Education (GME) payments from Medicare paid to offset the costs of training full time equivalent (FTE) residents and intern physicians (. *(Kaiser Foundation Hospitals v. Sebelius, Case # 12-5037*).

In 1997, Congress capped GME payments so that the number of FTE residents and interns the hospitals trained in 1996 would determine the maximum payments in all future years. The Department of Health and Human Services (HHS) agreed with Kaiser that the 1996 data for these hospitals was inaccurate. However, HHS refused to consider Kaiser's request to correct the data, arguing that no adjustments could be made since the three-year reopening window had passed.

Representing Kaiser before the Provider Reimbursement Review Board (PRRB), HLB attorneys successfully argued that it was not necessary to reopen the cost reports in question in order to recalculate the data and reimburse Kaiser appropriately. Although the PRRB agreed with the Kaiser position, the CMS administrator reversed the PRRB decision. HLB then sued HHS on behalf of Kaiser in U.S. District Court.

The district court ruled in Kaiser's favor, concluding that modifying FTE counts in closed years did not constitute a "reopening" of the cost reports. Based on arguments presented on Kaiser's behalf, the court also noted that HHS had a weak argument given that it had taken contrary positions in similar cases. HHS appealed the district court decision.

In its appeal, HHS argued that changes to cost report data for closed years would constitute a reopening under Section 405.1885. In addition, HHS argued that even if revising the FTE data in the closed years

didn't constitute a reopening, the change would require an adjustment to reimbursement for those years, which would constitute an impermissible reopening.

The appeals court disagreed with HHS' position. Citing, among other things, an HHS position in a 2009 case, the court ruled that "the reopening regulation allows for modification of predicate facts in closed years provided the change will only impact the total reimbursement determination in open years. " The court further agreed with the district court that HHS has acted arbitrarily by taking conflicting positions about the scope of the reopening rule in similar cases. In addition, the appeals court agreed with the district court that HHS offered no legal support for claims that caps cannot be increased without modifying the total reimbursement for closed years.

If HHS does not seek rehearing in the case before the Court of Appeal or review by the United States Supreme Court, the matter will be remanded to the district court so that the court can oversee the recalculation of the Kaiser providers' respective GME reimbursement using the proper number of intern and resident FTEs.

For additional information, please contact Jordan Keville in Los Angeles at 310.551.8111.

HLB Welcomes New Associates

Hooper, Lundy & Bookman is pleased to announce the addition of two new associates to the firm .

Ariana I. Ornelas

Based in the firm's Washington, D.C. office, Ariana I. Ornelas is a member of the firm's Regulatory Department. She was admitted to the New York Bar in 2008. She received a B.A. degree magna cum laude from Harvard University in 2004 and a J.D. degree from Harvard Law School in 2007.

Ms. Ornelas brings with her significant hospital expertise, having previously served as assistant general counsel for the Greater New York Hospital Association.

Her broad range of experience assisting health care providers includes providing strategic regulatory and policy advice with respect to federal and state self-referral and anti-kickback laws, Medicare/Medicaid coverage and billing requirements, as well as HIPAA and health IT privacy and security. She also has experience with FDA regulations and intellectual property litigation.

Ms. Ornalis is on the Young Professionals Council for the American Health Lawyers Association and is on the Young Professionals Advisory Board for the American Bar Association HIV Law Project.

She may be reached at 202.580.7703 or aornelas@health-law.com.

Lillie A. Werner

Based in the firm's Los Angeles office, Lillie A. Werner is a member of the firm's Litigation Department. She was admitted to the California Bar in 2008. She received a B.S. degree from the Massachusetts Institute of Technology in 2005 and a J.D. degree from Stanford Law School in 2008.

Ms. Werner brings with her a broad range of health care experience, including handling business disputes, class action and derivative litigation, regulatory and governmental investigations and white collar criminal defense.

She is admitted to the 9th Circuit Appellate Courts in the Central and Northern districts of California.

She may be reached at 310.551.8130 or lwerner@health-law.com.

CMS Announces Round Two of Innovation Awards

On May 15, the CMS Innovation Center released a funding opportunity announcement for its second round of Health Care Innovation Awards. According to CMS, the Innovation Center will spend up to $1 billion for awards and evaluation of projects from across the country that test new pay-

ment and service delivery models designed to deliver better care and lower costs for Medicare, Medicaid and the Children's Health Insurance Program (CHIP).

In this second round of awards consideration, CMS has tightened its focus and is seeking models in the following four categories:

- Models designed to rapidly reduce Medicare, Medicaid and/or CHIP costs in outpatient and/or post acute settings.
- Models that improve care for populations with specialized needs.
- Models that test approaches for specific types of providers to transform their financial and clinical models.
- Models that improve the health of populations – defined geographically, clinically, or by socioeconomic class through activities focused on engaging beneficiaries in prevention, wellness, and comprehensive care that extend beyond the clinical setting.

Within each of the four categories noted above, CMS highlights certain priority areas on which they are interested.

Eligible applicants include provider groups, health systems, payers and other private sector organizations, faith-based organizations, states, local governments, public-private partnerships and for-profit organizations.

CMS will host informational webinars for applicants. The following are important deadlines:

- Letter of Intent to Apply Due: June 28, 2013 ***by 3:00 pm EDT***
- Application Due: August 15, 2003 ***by 3:00 pm EDT***
- Anticipated Award Announcement: January 2014

Many applicants unfamiliar with the complicated Grants.gov process encountered difficulties during the very quick application timeframe in Round 1. We encourage individuals to seek counsel on ideas and process before diving into the complex procedure. Even if a potential applicant is not 100 percent certain of filing an application, filing a letter of intent will keep that door open until the application deadline.

For more information or guidance on the Health Care Innovation Awards process, please contact Marty Corry, Kelly Lavin or Alex Brill of our Government Relations and Public Policy Practice at 202.580.7700.

Calendar

May	**9**	**ABA Long-term Care Webinar** Mark Johnson presented *Compliance Programs for LTC Facilities*
	15-17	**ABA 23rd Annual Institute on Health Care Fraud, Miami Beach** Robert Roth presented *The Foundations of Health Care*
	30	**CAMSS Annual Education Forum, San Diego** **Jennifer Hansen presented Physician Behavior Contracts**
June	**6,12,13**	**CHA Hospital Finance & Reimbursement Seminar, Sacramento, Glendale, Irvine.** HLB Attorneys are lead faculty for this seminar. Lloyd Bookman and John Hellow present.
June	**10**	**2013 Los Angeles Regional Symposium: Reducing Hospital Readmission of the Chronically Ill Homeless** Charles Oppenheim and Glenn Solomon co-present *Why Hospitals Need to Focus on Readmissions Now*
June	**13**	**G2 Intelligence MDx Next: Gaining Ground in Molecular Testing and Genomic Medicine, Las Vegas** Patric Hooper presents *Molecular Diagnostic Payment: Policy and Practical Implications for Labs and Consumers and participates on a panel on What's Now and What's Next for MDx?*

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