HLB
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Newsletter
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Compliance with the HITECH Omnibus Rule: Checklist and Summary of Recent HHS Guidance

By Paul T. Smith, Esq. & Amy M. Joseph, Esq.

September 23 was the compliance date for the HITECH Omnibus Rule issued by the Department of Health and Human Services (HHS) on January 25 of this year.[1] This article provides a summary checklist of the actions that HIPAA-covered entities and their business associates should be taking to comply with the regulations, as well as a summary of the enforcement delays and guidance issued by HHS during the week prior to the compliance date.

Compliance Checklist

I. *Notice of Privacy Practices*

The rule requires covered entities to make the following changes to their notices of privacy practices by the compliance date. The Office for Civil Rights (OCR) and Office of the National Coordinator for Health Information Technology have just posted model Notice of Privacy Practices for health care providers and health plans.[2] If you prefer just to amend your current notice, these are the required changes:

> If the covered entity uses protected health information (PHI) for fundraising, its notice of privacy practices must inform individuals that they have the right to opt out of fundraising solicitations.
>
> The notice must inform individuals of the covered entity's obligation to notify them following a breach of unsecured protected health information.
>
> Currently, the notice must advise the individuals of their right to request restrictions on use or disclosure. It must also include a statement that the covered entity is not required to comply with the request. This second statement must now state that the covered entity is required to comply with a request not to disclose healthinformation to a health plan for payment or health care operations where the individual pays out-of-pocket for a service.
>
> If the covered entity intends to use or disclose psychotherapy notes in circumstances requiring authorization, or to use or disclose PHI for marketing, or to sell PHI, the notice of privacy practices must inform the individual that an authorization is required for these purposes.
>
> If the covered entity is a health plan that intends to use or disclose PHI for underwriting purposes, the notice must contain a statement that the plan is prohibited from using or disclosing genetic information for such purposes.

The notice of privacy practices no longer has to inform patients that the covered entity may contact them to provide appointment reminders or information about treatment alternatives or health-related benefits or services. However, there is no requirement that this be removed.

HHS says that these changes are material, and they therefore trigger the requirements for notification in the event of a material change. Health care providers must provide the revised notice to all new patients and to anyone else on request, and post it and make it available at their service delivery sites and on their web site if they maintain one. Previously, health plans were required to notify covered individuals within 60 days of a material revision to the notice. For health plans that have a web site this is replaced with a requirement to post the revised notice on the web site, and to include it in the next annual mailing to covered individuals. A health plan that does not have a web site must still provide the revised notice, or information on how to obtain it, within 60 days.

In This Issue

II. *Business Associate Agreements*

The new rule requires covered entities to amend their business associate agreements.[3] The implementation rules are as follows:

Business associate agreements that were entered into before January 23, 2013, and were not renewed or modified after March 26, 2013 must be amended by the *earlier* of either: (i) the date the contract or arrangement is renewed or modified after September 23, 2013; or (ii) September 22, 2014.

Other business associate agreements must be amended to conform to the new requirements by September 23, 2013, and all business associate agreements entered into, renewed or modified after September 23, 2013 must comply with the regulation.

III. *Policies, Procedures and Training*

HIPAA requires covered entities to implement policies and procedures to comply with the rules, and to change their policies and procedures as necessary and appropriate to comply with changes in the rules. HIPAA also requires covered entities to train affected workforce whose functions are affected by a material change in policies and procedures. Here is a summary of significant changes that will likely affect policies and procedures:

Data breach reporting. The rule changed the standard for determining whether a report is required: it replaced the "significant risk of harm" standard with a presumption that a breach is reportable unless the covered entity demonstrates that there is a low probability that the protected health information has been compromised, based on a risk assessment. Covered entities and their business associates should revise their data breach notification policies to reflect the new standard.

Sale of Protected Health Information. Formerly, the privacy rule did not prohibit a covered entity from receiving payment for PHI where the rule otherwise permitted the disclosure. Now it does, with some exceptions. Covered entities need a policy implementing this change.

Marketing. The HITECH rule eliminated the ability of a covered entity to receive remuneration for the following treatment or health care operations communications: (1) communications to describe a health-related product or service that is provided by the covered entity; (2) communications for the treatment of an individual, and (3) communications for case management or care coordination for the individual. Under the revised rule, a covered entity can still make these communications, but it cannot receive remuneration for doing so without an authorization from the individual. The rule has an exception for communications that describe a drug or biologic currently prescribed, such as a refill reminder, as long as any payment received by the covered entity for making the communication is reasonably related to the cost of making the communication (so no profit margin is permitted). However, California law, which also prohibits remunerated marketing, does not have this exception.

Fundraising. Covered entities that use PHI for fundraising will need to change their policies, as well as their notices of privacy practices:

- The rule formerly required fundraising solicitations to notify the patient of his or her right to opt out of future solicitations; now this must be in the notice of privacy practices, and the rule has new provisions on the implementation and effect of an opt-out that should be reflected in policies and procedures.

- The final rule also describes in more detail the types of PHI that a covered entity may use for fundraising purposes. Previously the rule allowed use of demographic information and dates of service only. It now also permits covered entities to use department of service information, including the treating physician, outcome information, and health insurance status. It now also says what it means by demographic information--this includes an individual's name, address, other contact information, age, gender and date of birth.

Disclosure of immunization proof to schools. HIPAA now allows this with the informal consent of the parent or guardian if the school is required by law to obtain it. Previously, a formal authorization would have been required.

Decedents. The amendments allow a covered entity to discuss health information about decedents with friends and family, unless the covered entity knows that this would be inconsistent with the decedent's previously expressed preferences. The amendment also removes all protections on PHI of persons who have been deceased for 50 years.

Genetic Information. Health plans are now prohibited from using genetic information for underwriting purposes. Health care providers may, however, use and disclose genetic information for treatment and other permitted purposes.

Research Authorizations.

- A covered entity may now combine conditioned and unconditioned research-related authorizations, as long as the authorization distinguishes between the two categories and allows the individual to opt in to the unconditioned research activities. For example, a single authorization could now cover a clinical study that includes both treatment (a conditioned authorization) and tissue banking of specimens (an unconditioned authorization).

- A research authorization need no longer be study-specific, and may also encompass future research.

Individual Rights. In addition to revising their notices of privacy practices, covered entities will need to revise some policies and procedures relating to individuals' rights:

- As a general rule, covered entities are not required to agree to requests for additional restrictions on otherwise permitted uses and disclosures of PHI. Now, however, health care providers must comply with the request of an individual not to disclose PHI to a health plan if the disclosure is for payment or health care operations (but not treatment), and the individual pays out of pocket in full for the service to which the information relates.

- If a covered entity maintains PHI in an electronic designated record set, an individual now has the right to obtain a copy of the PHI in an electronic form and format requested by the individual, if such form is readily producible. If the form requested is not readily producible, the covered entity must provide access in another readable electronic form as agreed to by the covered entity and the individual (e.g., MS Word, Excel, text, HTML, text-based PDF). The individual may also direct the covered entity to transmit the electronic copy directly to the individual's designee. The request must be in writing, signed by the individual, and must clearly identify both the designee and where to send the copy of PHI.

IV. *Business Associates*

Business associates must—

Comply with the HIPAA Security Rule.

Implement formal business associate contracts with their subcontractors.

Comply with the data breach reporting rule.

Business associates are also now legally required to comply with the core privacy provisions of their business associate contracts including, for example, provisions restricting the business associate's use and disclosure of PHI. Although the regulation does not require policies and procedures implementing these requirements, they are an important instrument of compliance, and business associates should consider developing them.

Recent Enforcement Delays and Guidance Issued by HHS

I. *Enforcement Delay for Certain Laboratories to Revise Notice of Privacy Practices*

On September 19, the Office for Civil Rights (OCR) announced that it would delay enforcement of the requirement to update notices of privacy practices for HIPAA-covered clinical laboratories that are certified or exempt from certification under CLIA (the Clinical Laboratories Improvement Amendments of 1988), and that are not required to provide individuals direct access to their laboratory reports. This is because OCR anticipates that an amendment to the HIPAA Privacy Rule and the CLIA regulations will be issued soon dealing with direct access to test reports, and wants to spare laboratories the burden and expense of successive updates to their notices. OCR says it will issue a further notice at least 30 days before the notices must be amended.
This enforcement delay does not apply to laboratories that do not have their own laboratory-specific notice of privacy practices, such as laboratories that are part of a hospital. Clinical laboratories that opt not to revise their notices now should monitor the OCR web site so that they are aware of when OCR ends this enforcement delay.[4]

II. *Guidance and Enforcement Delay on Refill Reminders and Marketing*

As referenced above, generally, a covered entity is required to obtain a written authorization before using protected health information to make a marketing communication, which is a communication that encourages the recipient to purchase or use a product or service. The rule allows some treatment-related communications, as long as the covered entity does not receive remuneration for making them. A covered entity may, however, be paid for communications about refill reminders and other communications about a drug or biologic currently being prescribed to an individual, as long as the remuneration is reasonably related to the covered entity's cost of making the communication.

On September 19, HHS issued guidance on when the refill reminder exception applies, and delayed enforcement of the restrictions on remunerated refill reminders until November 7, 2013.

The guidance says that covered entities must ask two questions: (1) Is the communication about a currently prescribed drug or bio-

HLB Briefs

HLB is pleased to announce that ***Stanton J. Stock*** has joined the firm's San Diego Office as an Associate in the firm's Litigation Department. Mr. Stock may be reached at sstock@health-law.com.

logic? and (2) Does the communication involve financial remuneration, and if so, is the financial remuneration reasonably related to the covered entity's cost of making the communication?

The guidance discusses the types of communications that fall within the refill reminder exception. Examples include communications about a generic equivalent to a drug being prescribed, and communications about recently lapsed prescriptions. However, the exception does not cover communications about new formulations of a currently prescribed drug, or communications encouraging an individual to switch to an alternative medicine.

As to the limit on financial remuneration, the guidance permits non-financial or in-kind remuneration, such as supplies or computers. It also allows payments by third parties unconnected with the drug supplier, such as a health plan. Payments from the supplier, however, are limited to the reasonable direct and indirect costs (labor, materials, supplies, capital and overhead costs) of making the communication.

As part of the guidance, HHS provides examples of situations where the communication falls within the exception, and also provides a comprehensive list of frequently asked questions.[5]

California providers should be aware that California law on remuneration for these kinds of communications is stricter than HIPAA. California's Confidentiality of Medical Information Act (Civil Code § 56) generally prohibits the use patient medical information for remunerated marketing. There are some narrow exceptions that allow a health plan to communicate with enrollees about more cost-effective pharmaceuticals, and that permit communications about treatment options to patients in disease management programs for chronic and serious conditions, as long as the recipient is given the opportunity to opt out of receiving future remunerated communications. As a general rule, however, California providers may not receive any remuneration for sending refill reminders.

III. *Guidance Regarding Protected Health Information of Deceased Individuals and Student Immunizations*

Also on September 19, HHS released guidance on two additional topics: health information of deceased individuals, and disclosure of student immunization information to schools.

In the guidance regarding PHI of deceased individuals, HHS explains that the lift of HIPAA protection on health information fifty years after death is intended to balance the privacy interests of surviving relatives with the need for others to access old records for historical purposes. The guidance also summarizes the existing privacy exceptions that apply just to deceased persons, such as providing information to coroners, funeral directors and organ procurement agencies.[6]

As to student immunizations, covered entities may now disclose proof of immunization directly to a school that is required to have such proof prior to admitting a student, if the covered entity has the oral or written agreement of a parent or guardian. HHS notes that this disclosure is permitted in the interest of public health and safety, as schools can help prevent the spread of communicable diseases by requiring immunizations. HHS emphasizes that a covered entity does not need a written authorization or other signed document to disclose such information. As one example, it is sufficient if a parent calls the provider to request disclosure, and the provider notes the conversation in the child's medical record.[7]

Hooper, Lundy & Bookman assists clients with a range of HIPAA compliance activities, including compliance counseling, policies and procedures, workforce training and managing data breaches. Keep up to date with developments in health information privacy, security and technology at our blog, www.hlbhitblog.com.

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

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[1] Our summary, with a link to the rule, is available at www.health-law.com/wp-content/uploads/2013/01/HITECH_Summary_2_1-23-13.pdf.

[2] *See* http://www.healthit.gov/providers-professionals/model-notices-privacy-practices. See also Section II.D.

[3] Our form of business associate agreement containing just the required provisions, with the required amendments underlined, is available at www.health-law.com/wp-content/uploads/2013/03/BAA_HLB_Business_Associate_Agreement_3-13.pdf. HHS has also published a form. See http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html.

[4] The statement of delay is available at http://www.hhs.gov/ocr/privacy/hipaa/enforcement/clia-labs.html.

[5] The guidance is available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/marketingrefillreminder.html.

[6] The guidance is available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/decedents.html.

[7] The guidance is available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/studentimmunizations.html.

Covered California's Enrollment Assistance Program

By Kaitlyn Halesworth, Esq. & Katrina A. Pagonis, Esq.

As we approach open enrollment for California's Health Benefit Exchange (Covered California) and other health insurance Exchanges nationwide, many providers are exploring their potential role in expanding coverage through patient outreach and enrollment assistance activities. Both Federal and California regulations create significant opportunities for providers to directly facilitate the enrollment of individuals and families in qualified health plans through the Exchange.

In July, the Department of Health and Human Services (HHS) finalized regulations that require each Exchange to work with Navigators and Certified Application Counselors and permit Exchanges to work with non-Navigator assistance personnel (also known as in-person assisters). All three types of entities will engage in enrollment assistance activities, and providers in every state should be eligible to facilitate Exchange enrollment through trained, Certified Application Counselors. Navigators and non-Navigator assistance personnel will have stricter eligibility requirements and duties, but may receive Exchange funding. (The former receive grants out of the Exchange operating budget while the latter may receive compensation from State Exchange Establishment grants.) For Federally-Facilitated Exchanges and Partnership Exchanges, HHS has awarded $67 million to 105 Navigator grantees beginning October 1.

Covered California recently finalized the creation of its Enrollment Assistance Program. The program is governed by emergency regulations that were approved on July 15, 2013.[1] The regulations create Certified Enrollment Entities and Certified Enrollment Counselors that will operate through the In-Person Assistance Program (IPA Program). The regulations are effective until January 14, 2014, by which time Covered California expects to enact more comprehensive enrollment assistance regulations that will include California's Navigator program. Certified Enrollment Entities and Certified Enrollment Counselors have broad enrollment assistance responsibilities that include providing applicants with information about the Exchanges and Medicaid and facilitating an applicant's selection of a qualified health plan.

Certified Enrollment Entity Eligibility and Application Process

Health care providers are generally eligible to become Certified Enrollment Entities. The regulations establish that licensed health care clinics, institutions, and providers; county departments of public health, city health departments, or county departments that deliver health services; faith-based organizations; non-profit community organizations; and trade, industry, and professional organizations are all eligible to apply to become Certified Enrollment Entities. Health insurance issuers, their subsidiaries, and their professional or trade associations, however, are prohibited from serving as Certified Enrollment Entities or Certified Enrollment Counselors. Likewise, entities and individuals that receive consideration from insurers in connection with enrollment activities (e.g., brokers that receive commissions) are ineligible to serve as Certified Enrollment Entities or Certified Enrollment Counselors. Covered California is expected to finalize rules concerning the activities of commissioned agents and brokers by the end of August.

Covered California recently made available a web-based IPA Program Certified Enrollment Entity Application. The application and a checklist of information required for the application can be accessed at: https://assisters.ccgrantsandassisters.org/. The application seeks general information about the entity, the populations it will serve, its primary site and sub-sites, its Certified Enrollment Counselors, and financial information (should the entity receive compensation). In addition, an entity must submit proof of general liability, automobile, and workers compensation insurance. The general liability and automobile insurance must each provide coverage of not less than $1,000,000 per occurrence with the Exchange named as an additional insured. Each Certified Enrollment Counselor to be affiliated with the entity must also pass a fingerprinting and criminal background check.

Once Covered California approves an application, the Certified Enrollment Entity may register for training. Individual Certified Enrollment Counselors are eligible for training after completing the background check. Training will only be provided by Covered California, and Covered California has begun accepting registrations for trainings that will begin in September. The training is designed to ensure that counselors are able to advise consumers on both the individual Exchange and the Small Business Health Options Program Exchange. The training will cover a wide range of topics, including insurance affordability programs (Medicaid, CHIP, premium assistance tax credits, and cost-sharing reductions), the tax implications of enrollment decisions, eligibility and enrollment rules and procedures, privacy and security standards for handling and safeguarding consumers' personally identifiable information, and outreach and education methods and strategies. Certified Enrollment Counselors must pass the exam annually to maintain certification with Covered California.

Compensation

Limited compensation is generally available to Certified Enrollment Entities, but most health care providers will be ineligible for compensation through Covered California. In general, upon successful enrollment of a consumer in a qualified health plan, a Certified Enrollment Entity will be compensated as follows: (1) $58 for each initial application during open or special enrollment; (2) $58 for each re-enrollment application; and (3) $25 for

each renewal application. With limited exceptions, however, licensed health care clinics, institutions, and providers are ineligible for compensation. Likewise, county departments of public health, city health departments, county departments that deliver health services, entities that the Exchange determines have a conflict of interest, and other entities that receive direct or indirect consideration for consumer assistance generally may not receive compensation. Nonetheless, community clinics, free clinics, Federally Qualified Health Centers and their look-alikes, Urban Indian Health Centers, and certain clinics and facilities affiliated with the Indian Health Service are eligible for compensation in connection with consumer application and enrollment assistance.

It is unclear whether a provider-affiliated entity that is not licensed to provide health care services may receive compensation. This question was posed to Covered California staff members at least as early as February 2013, but Covered California has not yet clarified the rules concerning affiliated entities. Non-profit community based organizations and faith-based organizations are both eligible to serve as Certified Enrollment Entities. Thus, it appears that a non-profit foundation affiliated with a hospital may be eligible to serve as a compensated Certified Enrollment Entity unless Covered California determines that its provider-affiliation constitutes a conflict of interest.

Steerage and Marketing

Both health care providers and applicants have an interest in assuring that applicants receive adequate information concerning each plan's provider network. Qualified health plans offered through Covered California will generally use narrow or tiered provider networks, so there is a risk that an uninformed applicant will enroll in a plan with which the applicant's preferred hospital or provider does not participate or participates at a higher cost-sharing tier. Such enrollments would be to the detriment of both the provider assisting with the enrollment and the applicant.

Certified Enrollment Entities and Certified Enrollment Counselors, however, must exercise caution when offering provider network information to consumers to assure that they do not steer them toward particular plans. The regulations specifically prohibit "[c]oach[ing] or recommend[ing] one plan or provider over another." It appears, however, that mere information sharing concerning contracted plans is permissible. In fact, Certified Enrollment Entities and Certified Enrollment Counselors are required to disclose to consumers "any existing or anticipated financial, business, or contractual relationships" with health insurance issuers or stop loss insurance issuers as well as their subsidiaries. This disclosure will inherently result in identifying contracted plans.

The Covered California regulations also limit marketing activities that might induce enrollment. In particular, Certified Enrollment Entities and Certified Enrollment Counselors are prohibited from paying any part of the premium or any other type of consideration to or on behalf of a consumer. Some of these activities may raise additional concerns under Federal and State fraud and abuse laws insofar as many qualified health plans will be subsidized by Federal funding through premium assistance tax credits and cost-sharing reductions.

Hooper, Lundy & Bookman is in the process of advising clients on opportunities to become involved in consumer assistance activities through Covered California and other states' Exchanges, including providing guidance in connection with federal and state privacy and security laws implicated in these activities.

*For additional information, please contact Kaitlyn Halesworth, or Katrina A. Pagonis in San Franc*isco at 415.875.8500.

1 Cal. Code Regs., tit. 10, §§ 6650 – 6670, available at http://www.oal.ca.gov/res/docs/pdf/emergencies/recent%20action,%20moved%20emergencies/2013-0705-01E_App.pdf. Section 6656 is currently reserved for the Navigator Program Application, which has not yet been released.

Calendar

September 10

CAHF Region 2 Annual Meeting
Mark Johnson presented *Managing Managed Care*

September 12

HLB Webinar: Covered California: What Providers Need to Know Today About California's Health Insurance Exchange
Martin Corry, Amanda Hayes-Kibreab, Katrina Pagonis and Glenn Solomon presented. Playback link: http://www.infiniteconferencing.com/Events/Hooper%20Lundy/091213HLB/recording-playback.html

September 17

HFMA Northern California Fall Conference, Concord, CA
Felicia Sze and Amanda Hayes presented *Cal MediConnect: California's Dual Eligible Program.*

September 19

AHLA Plan-Provider Managed Care Contracting Webinar
Kitty Juniper co-presented

September 19

Strafford CLE Webinar:
Health Exchanges: Legal Risks & Proactive Strategies for Providers
Katrina Pagonis and Martin Corry presented

September 26, 27

The Conference on Health Reform, Las Vegas
HLB co-sponsors this event. John Hellow presents *Final Medicare Rule, Sequestration, Quality initiatives and Medicare Payments: Implications for Medicare Advantage and Commercial Payments;* Charles Oppenheim co-presents *ACOs and Other Structures for Physician Alignment*; Katrina Pagonis co-presents *Insurance Exchanges: Implications for the Hospital Marketplace;* Jordan Keville and Nina Adatia co-present *Litigation Update; Stephen Treadgold co-presents Tax Matters: Implementation of the New 990.* **Registration information: 317.631.3613.**

September 29-October 1

AHLA AND HCCA Fraud and Abuse Compliance Forum
Patric Hooper presents *False Claims Act Primer*; Robert Roth presents *Primer of Medicare/Medicaid Program Integrity: What the Government Can Do and How to Respond*

October 7, 8

AHCA Annual Convention, Phoenix
Mark Reagan presents *Adapting to Contract Requirements under Evolving Managed Care Requirements and Sequestration;* Mark Reagan and Mark Johnson co-present *Medicare-Medicaid Integration Projects.*

October 10

LACBA 10th Annual Healthcare Law Compliance Symposium, Los Angeles
Charles Oppenheim and Nina Adatia present *Recent Compliance Issues in Healthcare Business Transactions.*

October 10 - November 2

2013 American Cancer Society Making Strides Walk
www.makingstrideswalk.org
The HLB Diversity Initiative announces the following locations and team captains: Washington, D.C. (10/6) Ariana Ornelas; San Diego (10/20) Jennifer Hansen; San Francisco (10/26) Kaitlyn Halesworth; Los Angeles (11/2) Tracy Jessner & Katie Dru.

Calendar

October 16

AHLA Brown Bag Webinar
What I know Now that I Wish I Knew Then: Career Choices in a Firm, Government and In-House Setting. Felicia Sze co-presents.

October 22, 23

HLB Presents The Changing Face of Hospital Managed Care Reimbursement: the Coordinated Care Initiative, Sequestration, and More, Los Angeles & Berkeley.
Daron Tooch, Mark Johnson, Alex Brill , Felicia Sze, Amanda Hayes-Kibreab present this program.
Information & Registration:
Los Angeles, October 22: https://www.etouches.com/eregnewregphp?eventid=72287&
Berkeley, October 23: https://www.etouches.com/ereg/newreg.php?eventid=72313&

October 23

HFMA Tennessee Chapter Fall Institute
Robert Roth Presents *The FFY 2014 IPPS Final Rule Disproportionate Share Hospital Payment Provisions*

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