HLB
HOOPER, LUNDY & BOOKMAN, INC.
HEALTH CARE LAWYERS

September 23, 2013

A Flurry of Activity from OCR as HITECH Omnibus Rule Compliance Date Approaches

Amy M. Joseph
Paul T. Smith

The September 23 compliance date for the HITECH Omnibus Rule has arrived, and in anticipation the Department of Health and Human Services (HHS) has released a flurry of guidance within the past week, including enforcement delays on two requirements.

Enforcement Delay for Certain Laboratories to Revise Notice of Privacy Practices

The Omnibus Rule makes changes to the privacy obligations of covered entities, and covered entities are required to make corresponding revisions to their notices of privacy practices (NPPs) by September 23.

On September 19, the Office for Civil Rights (OCR) of HHS announced that it would delay enforcement of the requirement to update NPPs 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 NPPs. 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 NPPs, such as laboratories that are part of a hospital. Clinical laboratories that opt not to revise NPPs now should monitor the OCR web site so that they are aware of when OCR ends this enforcement delay. The statement of delay is available here.

Guidance and Enforcement Delay on Refill Reminders and Marketing

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 biologic? 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 communication 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. The guidance is available here.

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.

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.

The Omnibus Rule made two changes affecting deceased persons: One was to allow covered entities to disclose health information to family and friends. The other was to lift the HIPAA protection on health information altogether fifty years after death. HHS states that this 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. The guidance is available here.

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. The guidance is available here.

Our summary of the Omnibus Rule, along with a link to the rule, is available here. In addition, we recently prepared a summary checklist for complying with the rule, available here.

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.

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 t 310.551.8111; and in Washington, D.C., Robert Roth or Ariana Ornelas at 202.580.7700.