

July 2010 / Special Alert

A legal update from Dechert's Employee Benefits and Executive Compensation and Health Law Groups

DHHS Proposed Rule Implements the HITECH Act and Amends HIPAA Rules

The Department of Health and Human Services ("DHHS") recently published a notice of proposed rulemaking (the "Notice") to modify the privacy, security and enforcement rules issued under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The Notice has two purposes: (1) implementing various provisions of the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act") which was part of the American Recovery and Reinvestment Act of 2009; and (2) making various other changes to the HIPAA rules.

Business Associates

The Notice would make a number of changes to the definition of "business associates," including treating subcontractors of business associates as business associates. Covered entities, however, would not be required to have business associate agreements directly with their business associate's subcontractors. Currently, business associates are required by contract to have their subcontractors agree to the same restrictions and conditions that apply to business associates. Under the proposed rule, business associates must obtain full, written business associate contracts with their subcontractors to whom they provide protected health information ("PHI"). Also, just as a covered entity would need to act when it learns of a pattern or practice constituting a material breach by a business associate of its business associate agreement, so would the business associate be required to act to remedy the situation if it learns of a subcontractor's pattern or practice constituting a breach of its agreement with its subcontractor. The Notice would eliminate the requirement that covered entities report to the DHHS if termination of a business associate agreement is not feasible after a breach by the business associate.

Business Associate Agreement Changes

In addition to the subcontractor provision described above, the Notice would require a number of changes to business associate agreements, including:

- Replacing the existing security rule safeguard provision with new language requiring business associates to comply with the security rule;
- Requiring business associates to report to covered entities regarding breaches of unsecured protected health information, including security incidents; and
- Requiring business associates to comply with requirements of the privacy rule to the extent that business associates are required to carry out covered entities' obligations under the privacy rule.

Transition Time

The Notice would permit covered entities and business associates to continue to operate under existing, currently compliant business associate agreements for up to one year and 240 days after the publication date of the final

regulation, unless the agreement is renewed or modified sooner.

Business Associate Compliance/Penalties

The Notice implements the HITECH Act's requirement that business associates that violate applicable provisions of the security rule are subject to the same civil and criminal penalties as are covered entities.

Covered Entity Responsibility for Business Associates

Similar to the breach reporting regulations, the Notice would make a number of changes that would make a covered entity directly liable for the actions of business associates who are "agents" under common law. To the extent a business associate is an independent contractor and not an agent of the covered entity, the covered entity would be liable only if it becomes aware of a "pattern or practice" in violation of the rules and does not take action to remedy the situation.

Privacy Rule Changes

Compound Authorizations and Authorizations for Future Research

Researchers had voiced concerns regarding the privacy rule's prohibition on combining a conditioned authorization (for use and disclosure of PHI for a research study) with a non-conditioned authorization (such as for tissue banking of specimens for future research). Apparently, this prohibition has resulted in multiple authorizations for clinical trials and related activities, sometimes confusing individuals who are considering participating in clinical trials. In response to these concerns, the Notice would permit covered entities to combine a conditioned authorization for use of PHI in a clinical trial with an unconditioned authorization permitting inclusion of the individual's PHI in a central repository, as long as the authorization clearly differentiates between the conditioned and unconditioned research components and offers an opt-out for the unconditioned research activity. DHHS also requests comments on whether to relax the rule that research authorizations be research-specific. This would permit use of data or banked tissue for future research, without the need to go back to the individual for an authorization for a specific research project, or to obtain a waiver of authorization from an institutional review board or a privacy board.

Immunization Information

The existing privacy rule requires a formal, written authorization for a provider to furnish health information about a student to his or her school. The Notice would permit a provider to disclose proof of immunization to a school, if the school is required by law to obtain the information to admit the student, and the provider obtains consent (including oral consent) from the student's parent or guardian.

Decedents

The privacy rule protects PHI of decedents in the same way as it does for living persons. In particular, the PHI of deceased persons may be disclosed only to the individual's personal representative, but not to other family members or friends. The Notice would permit a covered entity to disclose PHI to a family member or friends involved in the person's care or payment for care, unless doing so is inconsistent with a prior expressed preference of the individual. In addition, no privacy protection would apply to PHI of persons deceased for more than 50 years.

Notice of Privacy Practices

The Notice would require several new topics to be addressed in notices of privacy practices. In particular, in addition to existing content requirements, these notices must:

- Describe the types of uses and disclosures that require an authorization;
- Disclose whether the covered entity intends to send subsidized treatment communications and notify individuals of the right to opt out;
- If the covered entity intends to send fundraising solicitations, the notice must notify individuals of the right to opt out;
- Describe the need for an authorization for uses of psychotherapy notes, marketing, and the sale of PHI for which authorization is required; and
- Inform individuals that the covered entity may not refuse a request to withhold information from a health plan when the individual pays in full for the service.

Request for Restrictions on Disclosures to Health Plans

The Notice implements the HITECH Act requirement that covered entities must agree to requests for restrictions on use or disclosure of PHI to a health plan for purposes of carrying out payment or health care operations when the PHI pertains solely to a health care item or service for which the provider has been paid out of pocket in full. The Notice requests comments on whether providers should have to notify downstream providers of the restrictions, including how providers who use electronic prescribing may alert a pharmacy of the restriction, so that the pharmacy does not submit a claim to the health plan for drugs related to the restricted service.

Minimum Necessary Use and Disclosure

The Notice implements the HITECH Act provision requiring covered entities to limit their uses, disclosures and requests for PHI to the extent practicable, to a limited data set. The Notice indicates that covered entities should consider the feasibility of using the limited data set, but are not required to do so.

Right to Receive Electronic Copies

The HITECH Act provides that when a covered entity uses or maintains an electronic health record regarding an individual, the individual has the right to obtain a copy of his or her PHI in electronic format. The DHHS notes that the HITECH Act expansion of the right to access applies only to information in electronic health records but expands the right further to PHI in other types of electronic records systems. In particular, the Notice provides that, if the PHI is maintained electronically in one or more designated record sets, the covered entity must provide the individual with access to PHI in the electronic form or format requested by the individual.

Sale of PHI

The HITECH Act prohibits a covered entity or business associate from directly or indirectly receiving remuneration in exchange for any PHI without a valid authorization from the individual. There are a number of exceptions to this prohibition (each with its own requirements), including if the purpose is for:

- Public health activities;
- Research;

- Treatment;
- Sale, transfer or merger, or consolidation of all or part of the covered entity and for related due diligence;
- Remuneration provided by a covered entity to a business associate for activities the business associate undertakes on behalf of the covered entity pursuant to a business associate agreement; and
- Providing an individual with a copy of his or her PHI.

The Notice implements these provisions and adds a number of requirements, including requiring that an authorization for sale of PHI must disclose that the covered entity will be receiving remuneration for the disclosure. The Notice also would allow a covered entity to receive payment for a disclosure required by law and permits the covered entity to charge a reasonable, cost-based fee to prepare and transmit health information for any purpose for which disclosure is permitted.

Marketing

The HITECH Act made a number of changes to existing privacy rule marketing provisions. Among other things, the HITECH Act prohibits a covered entity from receiving financial remuneration for making marketing communications (by itself or through a business associate) without an authorization, except where the communication describes a drug or biologic that is currently being prescribed for a person. Under this narrow exception, any payment received by the covered entity in exchange for making a communication must be “reasonable” as defined by the DHHS. Another exception to the prohibition is when the communication is made by a business associate on behalf of the covered entity and the communication is consistent with the business associate agreement between the business associate and the covered entity.

The Notice implements these requirements by distinguishing between treatment communications (which are not marketing and do not require authorization) and health care operations communications (which are marketing and require an authorization if they encourage a person to buy something). The DHHS concludes that population-based communications generally would be considered health care operations and therefore, would require authorization, while communications targeted to a particular person’s health care needs would be considered treatment-related, and would not

require an authorization. However, to ensure that the individual is aware that he or she may receive subsidized treatment communications from his or her provider and has the opportunity to elect not to receive them, the Notice would require a statement in the provider's notice of privacy practices stating that the provider intends to send such subsidized treatment communications and must offer an opportunity to opt out of such communications. The opt-out process cannot be burdensome (e.g., requiring a written letter). The DHHS requested comments on the scope of the opt out, including whether it should cover all future subsidized treatment communications, or just those concerning the particular product or service described in the current communication.

Fundraising

The HITECH Act requires the DHHS to provide by rule that any written fundraising communication must, in a clear and conspicuous manner, provide an opportunity for the recipient of the communications to elect not to receive any further such communications. The privacy rule provides that if an individual opts out the covered entity must make reasonable efforts to ensure that individuals who opt out are not sent such communications. The Notice implements the HITECH Act by prohibiting further fundraising communications from being sent to a person who has opted out of receiving such communications. Covered entities must include a statement of the person's right to opt out of such communications in its notice of privacy practices.

Moreover, the Notice notes that the opt-out mechanism must not require the individual to incur an undue burden or more than a nominal cost. Examples of compliant opt-out mechanisms include providing an e-mail address or toll free number. Requiring a written letter would be considered too burdensome. The DHHS also solicits comments on whether the information that can be used for fundraising (demographic information and dates of service) should be broadened to allow more targeted information, such as the department in which the individual received services.

Enforcement

The Notice makes a number of changes to the HIPAA enforcement rule, including having it apply directly to business associates. As required by the HITECH Act, the rule would require the DHHS to conduct a compliance review when a preliminary review of the facts of a complaint indicates a possible violation due to willful neglect. In addition a complaint is not necessary to trigger a formal investigation where the DHHS becomes aware of facts indicating willful neglect, regardless of whether a complaint has been submitted.



Comments regarding the proposed rule may be submitted to DHHS on or before September 13, 2010.

Practice group contacts

If you have questions regarding the information in this legal update, please contact the Dechert attorney with whom you regularly work, or any of the attorneys listed. Visit us at www.dechert.com/employeebenefits and <http://www.dechert.com/health>.

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