

HHS PUBLISHES FINAL CHANGES TO HIPAA PRIVACY RULE

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I. BACKGROUND

On Wednesday, August 14, 2002, the Secretary of the Department of Health and Human Services (“HHS”) published in the *Federal Register* revised Standards for Privacy of Individually Identifiable Health Information (“Final Rule”) under the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191 (“HIPAA”). Most health care entities must be fully compliant with the Final Rule by April 14, 2003.

The changes set forth in the Final Rule modify privacy standards originally promulgated in December 2000 (“Privacy Rule”), and are substantially similar to changes to the Privacy Rule proposed by HHS in a March 2002 Notice of Proposed Rulemaking (“March NPRM”). The Final Rule – available at www.hhs.gov/ocr/hipaa – is intended “to maintain strong protections for the privacy of individually identifiable health information while clarifying certain of the Privacy Rule’s provisions, addressing the unintended negative effects of the Privacy Rule on health care quality or access to health care, and relieving unintended administrative burdens created by the Privacy Rule.” Overall, the Final Rule’s biggest impact may be to ease the burden on providers by eliminating requirements regarding patient consent (see below), as had been proposed in the March NPRM. The Final Rule also extends the time for certain business associate contracts to come into compliance and streamlines limitations on marketing.

The following is a summary of some of the key changes in the Final Rule. Providers, plans, and other affected parties should review the Final Rule in its entirety to ensure HIPAA compliance.

II. CONSENT AND NOTICE

Under the Final Rule, health care providers with direct treatment relationships with individuals will no longer be required – as they were under the original Privacy Rule – to obtain an individual’s consent prior to using and disclosing information about him or her for treatment, payment, and health care operations. Instead, requiring consent is optional for health care providers.

To counterbalance the elimination of the consent requirement, the Final Rule amends the requirements regarding the provision of notice to patients. In particular, under the Final Rule, a covered health care provider with a direct treatment relationship must make a “good faith” effort to obtain an individual’s written acknowledgment of receipt of the provider’s notice of privacy practices. The Final Rule refrains from proposing a specific form for the acknowledgment, specifying only that it must be in writing. If an individual refuses to sign or otherwise provide an acknowledgment, a covered health care provider is required to document its good faith efforts to obtain the acknowledgment and the reason why the acknowledgment was not obtained.

III. DISCLOSURE OF PHI

In a further effort to ease the perceived administrative burdens of the Privacy Rule, the Final Rule broadens the uses and disclosures of protected health information (“PHI”) that are permitted as part of treatment, payment, and health care operations (collectively “TPO”). In particular, the Final Rule clarifies that a covered entity may (i) use or disclose PHI for its own TPO without prior consent or authorization; (ii) share PHI for the treatment activities of another health care provider; (iii) disclose PHI to another covered entity or health care provider for the payment activities of that entity; and (iv) disclose PHI about an individual to another covered entity for certain health care operations – namely, those involving quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management, conducting training programs, and accreditation, licensing, or credentialing activities. The Final Rule also clarifies that covered entities participating in an organized health care arrangement (“OHCA”) may share PHI for the health care operations of the OHCA.

IV. INCIDENTAL USES AND DISCLOSURES

The Final Rule permits certain incidental uses and disclosures that occur as a result of an otherwise permitted use or disclosure. The prototypical example of this situation is a confidential oral communication between individual providers or between a provider and a patient, if there were a possibility that the conversation could be overheard. HHS emphasizes, however, that “an incidental use or disclosure is permitted only to the extent that the covered entity has applied reasonable safeguards” to protect the information and “implemented the minimum necessary standard.”

V. MINIMUM NECESSARY

Certain aspects of the “minimum necessary” requirements are clarified in the Final Rule. For example, any uses or disclosures for which a covered entity has received an authorization that satisfies the Final Rule are exempt from the minimum necessary requirements. While refusing to make any sweeping changes, HHS notes in the Preamble of the Final Rule that it will “monitor the workability of the minimum necessary standard and consider proposing revisions, where appropriate.”

VI. BUSINESS ASSOCIATES

The Final Rule amends the Privacy Rule’s transition provisions to allow covered entities, other than small health plans, to continue to operate under certain existing contracts with business associates for up to one year beyond the April 14, 2003, compliance date. This provision applies to existing written agreements which are not renewed or modified between the effective date of the Final Rule – *i.e.*, October 14, 2002 – and April 14, 2003. A covered entity that enters into a contract after the effective date of this modification must have a business associate contract that meets the applicable requirements of the Final Rule. Moreover, even for existing contracts, the new provisions do not relieve a covered entity of the obligation to (a) make PHI held by a business associate available to HHS, (b) comply with an individual’s right to access, amend, or receive an accounting of the individual’s PHI held by a business associate, or (c) mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a wrongful use or disclosure of PHI by its business associate.

VII. MARKETING

The Final Rule simplifies certain aspects of the rules regarding marketing. For example, the disclosure and “opt out” provisions as formulated in the original Privacy Rule are eliminated. Instead, as a general matter, a covered entity must have an individual’s prior written authorization to use or disclose PHI for marketing communications. The definition of “marketing” has been modified to clarify that if no exception applies, and, “on its face, [a] communication encourages recipients of the communication to purchase or use the product or service, the communication is marketing.” With respect to prescription drugs, in particular, the Final Rule does not prohibit a provider from sending patients prescription refill reminders, even if a third party pays or subsidizes the communication, or even if a business associate assists in making the communications.

VIII. PARENTAL ACCESS TO MINORS’ RECORDS

The Final Rule includes certain clarifying changes to the original Privacy Rule designed to foster three goals with respect to parents and minors; specifically, ensuring that (1) parents have appropriate access to the health information about their minor children, while also ensuring that a minor still has the ability to consent to and obtain health care under applicable State or other applicable law; (2) State or other applicable law relating to competency or parental rights is not hindered; and (3) professional requirements of State medical boards or other ethical codes of health care providers are not encumbered. As a result, the Final Rule generally defers to State or other applicable law and professional practice with respect to parents and minors.

IX. RESEARCH

The Final Rule makes several changes to the use and disclosure of PHI for research purposes. For example, the Final Rule consolidates the criteria originally set forth in the Privacy Rule that are used by an IRB or Privacy Board in determining whether to approve a waiver of authorization. The Final Rule also eliminates provisions specifically applicable to obtaining authorization for research purposes, relying instead on a single set of requirements generally applicable to all types of authorizations (see further discussion below). Authorizations also can be consolidated with other legal permissions related to a research study. In addition, the Final Rule eliminates the requirement for an expiration date for all uses and disclosures of protected health information for research purposes.

Finally, the Final Rule amends the transition provisions of the original Privacy Rule to permit a covered entity to use or disclose for a specific research study protected health information that is created or received either before or after the compliance date, if the covered entity has obtained, prior to the compliance date, an authorization or other express legal permission from an individual to use or disclose protected health information for the research study.

X. AUTHORIZATIONS

Under the Final Rule, implementation specifications for authorizations have been consolidated into a single set of criteria. These modifications permit covered entities to

use a single authorization form, and facilitate greater ease of use for individuals and covered entities, as well as third parties.

XI. LIMITED DATA SETS

In the March NPRM, HHS requested comment on a means of permitting uses and disclosures of limited data sets of PHI which does not include facially identifiable information but in which certain identifiers would remain. In response to comments, the Final Rule endorses the use of limited data sets for disclosures for research, public health, and health care operations purposes. Before disclosing such information, however, the covered entity and the recipient of the information must enter into a “data use agreement” in which the covered entity obtains satisfactory assurance that the PHI in the limited data set will be protected. See 45 C.F.R. § 164.512(e).

XII. OTHER CHANGES

Among other changes and clarifications set forth in the Final Rule are the following:

- The definition of PHI is amended to specifically exclude employment records maintained by a covered entity in its capacity as an employer.
- Group health plans can disclose to a plan sponsor whether an individual is participating in the group health plan, or is enrolled or has disenrolled from a health insurance issuer or HMO offered by the plan, without having to amend plan documents.
- Covered entities no longer need to account for disclosures for which authorization has been obtained.
- Covered entities can disclose, without authorization, certain information about quality, safety and effectiveness of FDA-regulated products and activities to private entities subject to FDA jurisdiction, so long as the disclosure is made for a “public health” activity or purpose (as opposed to, e.g., marketing).

For further information related to your own situations and any specific legal questions you may have, contact your regular contact at Crowell & Moring or one of the following attorneys:

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