

SAMPLE

Final Privacy Rule

Publication Date: August 14, 2002

By and large, the final rule adopts the changes proposed in the March 2002 NPRM with few major differences. This summary focuses on modifications, additions and clarifications of the NPRM as they appear in the final rule. Of particular interest to pharmaceutical companies are the provisions and comments related to marketing, uses and disclosures regarding FDA regulated products and activities, and the "limited data set." Consequently, this summary includes further comments related to these issues.

Highlights of the Final Rule

Marketing -- The final Rule requires a covered entity to obtain an individual's prior written authorization to use his or her protected health information for marketing purposes except for a face-to-face encounter or a communication involving a promotional gift of nominal value. The Department makes clear that a covered entity is prohibited from selling lists of patients and enrollees to third parties or from disclosing protected health information to a third party for the marketing activities of the third party, without the individual's authorization. SEE COMMENTS.

Consent and Notice -- The Rule requires direct treatment providers to make a good faith effort to obtain patient's written acknowledgement of the notice of privacy rights and practices. The final Rule removes mandatory consent requirements that would inhibit patient access to health care while providing covered entities with the option of developing a consent process that works for that entity. The Rule also allows consent requirements already in place to continue.

Uses and Disclosures Regarding Food and Drug Administration (FDA)-Regulated Products and Activities -- The final Rule permits covered entities to disclose protected health information, without authorization, to a person subject to the jurisdiction of the FDA for public health purposes related to the quality, safety or effectiveness of FDA-regulated products or activities such as collecting or reporting adverse events, dangerous products, and defects or problems with FDA-regulated products. SEE COMMENTS.

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Limited Data Set -- The final Rule permits the creation and dissemination of a limited data set (that does not include directly identifiable information) for research, public health, and health care operations. In addition, to further protect privacy, the final Rule conditions disclosure of the limited data set on a covered entity and the recipient entering into a data use agreement, in which the recipient would agree to limit the use of the data set for the purposes for which it was given, and to ensure the security of the data, as well as not to identify the information or use it to contact any individual. SEE COMMENTS.

Comments on Specific Issues

Marketing

Definition

- (1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:
 - (i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.
 - (ii) For treatment of the individual; or
 - (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

- (2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Marketing – General Comments

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“While the Proposal requires patient consent before information can be disclosed for marketing, it renders this protection virtually meaningless by significantly narrowing the definition of marketing. As a result, the Proposal would allow disclosures of health information without a patient’s knowledge for a wide range of activities that the American consumer would consider marketing. For example, under the Proposal patients could receive unsolicited telephone calls and direct mail advertisements that encourage them to purchase new products or switch to alternative treatments. These telephone calls or direct mailings would be exempt from the definition of marketing even if the calls or mailings came from a drug company instead of a patient’s provider, and even if the drug company paid the provider for the patient’s sensitive medical information. Because these kinds of activities are exempt from the restrictions that apply to marketing, patients would be unable to prevent these unsolicited communications.” – HOUSE COMMITTEE LETTER²

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Disclosure to FDA-Regulated Entities

In the final modifications, the Department adopts the language proposed in the NPRM. Section 164.512(b)(1)(iii), as modified, permits covered entities to disclose protected health information, without authorization, to a person subject to the jurisdiction of the FDA with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety, or effectiveness of such FDA-regulated product or activity. Such purposes include, but are not limited to, the following activities and purposes listed in subparagraphs (A) through (D): (1) to collect or report adverse events (or similar activities regarding food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, (2) to track FDA-regulated products, (3) to enable product recalls, repairs, or replacement, or for lookback (including locating and notifying persons who have received products that have been withdrawn, recalled, or are the subject of lookback), and (4) to conduct post-marketing surveillance. – PREAMBLE TO FINAL RULE

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Incidental Use and Disclosure

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Incidental Use and Disclosure – Accounting for Incidental Disclosures

[TEXT DELETED IN SAMPLE]

Incidental Use and Disclosure – Conflict with Security Rule Over Safeguards

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Research

General

[TEXT DELETED IN SAMPLE]

Research – Expiration Date

[TEXT DELETED IN SAMPLE]

Research – Continued Use and Disclosure After Withdrawal

[TEXT DELETED IN SAMPLE]

Research – Blanket Authorizations

[TEXT DELETED IN SAMPLE]

Research – Recruitment for Clinical Trials

[TEXT DELETED IN SAMPLE]

Limited Data Set

[TEXT DELETED IN SAMPLE]

Limited Data Set – Data Use Agreement

[TEXT DELETED IN SAMPLE]

References

1. HEALTH PRIVACY PROJECT: Press Release – “HHS Releases Final Modifications to Privacy Rule” (8/9/2002)
2. HOUSE COMMITTEE LETTER: House Committee on Government Reform Letter to Secretary Thompson (7/23/2002)
3. HLC PR: Health Leadership Council Press Release: “Health Leaders Call Issuance of Final Privacy Regulations A ‘Landmark Day’ for Patients” (8/8/2002)
4. DWT PR: Davis Wright Tremaine Press Release – “DAVIS WRIGHT TREMAINE LLP RELEASES ANALYSIS & COMMENTS ON MAJOR CHANGES TO HIPAA PATIENT PRIVACY” (8/11/02)
5. HHS FACT SHEET: “Modifications to the Standards for Privacy of Individually Identifiable Health Information” (8/9/2002)