



FINAL AMENDMENT TO THE HIPAA PRIVACY RULE August 2002

On August 14, 2002, the U.S. Department of Health and Human Services (“HHS”) published in the Federal Register the final version of an amendment (the “Final Amendment”) to the HIPAA Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”). HHS had released a proposed amendment (the “Proposed Amendment”) for public notice and comment on March 21, 2002.

The Final Amendment basically tracks the Proposed Amendment, with certain minor changes. The Final Amendment does *not* defer the compliance date of the Privacy Rule, which remains April 14, 2003. It also has no effect on the transactions and code sets rule, which is scheduled to go into effect on October 16, 2002 for covered entities that do not file a compliance plan seeking a one-year extension. HHS has still not issued a final version of the HIPAA security rule.

This summary describes the most significant differences between the Final Amendment and the provisions of the Privacy Rule issued by HHS on December 28, 2000 (the “December 2000 Rule”). It also highlights the ways in which the Final Amendment differs from the Proposed Amendment. Please do not hesitate to contact us if you have any questions regarding the Final Amendment or require advice about any aspect of HIPAA.

* * * *

Health care providers are not required to obtain an individual’s consent to use or disclose protected health information for treatment, payment or health care operations.

Under the December 2000 Rule, in most cases health care providers were required to obtain an individual’s written consent before using or disclosing protected health information for treatment, payment or health care operations. Many providers complained that this was impractical in situations where the provider needs to use or disclose protected health information prior to a physical interaction with an individual in order to fill prescriptions, schedule surgery, obtain pre-certification for treatment or perform other legitimate functions.

The Final Amendment, like the Proposed Amendment, permits health care providers to use or disclose protected health information for treatment, payment or health care operations without the patient's consent. The December 2000 Rule already gave health plans this right. Health care providers have the option of obtaining consent, which may in some cases be required by state law. Instead of obtaining consent, as described below, health care providers must make a "good faith effort" to obtain the individual's written acknowledgment of receipt of the provider's privacy notice.

Covered entities may disclose protected health information to facilitate treatment, payment and health care operations of another entity without the individual's consent.

Under the December 2000 Rule, while covered entities could disclose protected health information to facilitate treatment by another covered entity, they had to obtain the individual's authorization for disclosures intended to facilitate the payment or health care operations of another entity. For example, a provider could not disclose information to a health plan that would be used by the health plan for quality assurance purposes without obtaining the individual's written authorization.

The Final Amendment, like the Proposed Amendment, relaxes this requirement by essentially expanding the definition of treatment, payment and health care operations to include the performance of these activities by other entities. Thus, covered entities may disclose protected health information to other entities without the individual's authorization in the following circumstances:

- For treatment or payment by any other covered entity or non-covered health care provider; and
- For certain health care operations of another covered entity, such as quality assessment and improvement activities; population-based activities relating to improving health or reducing health care costs; case management; conducting training programs; accreditation, certification, licensing or credentialing activities; and fraud and abuse detection and compliance.

Most health care providers must make a good faith effort to obtain a written acknowledgment of the patient's receipt of the provider's privacy notice.

The Privacy Rule requires covered entities to provide individuals with a privacy notice detailing the entity's privacy policies and practices. Under the December 2000 Rule, the privacy notice generally had to be distributed by health care providers in conjunction with obtaining the patient's consent for uses and disclosures of protected health information for treatment, payment and health care operations.

As indicated above, in conjunction with eliminating the consent requirement, the Final Amendment, like the Proposed Amendment, obligates health care providers with a direct treatment relationship (but not health plans or providers with an indirect treatment relationship) to make good faith efforts to obtain the patient's written acknowledgment of receipt of the privacy notice. This would generally take place at the first encounter after the Privacy Rule's

compliance date, which is when providers must distribute the notice. If an acknowledgment cannot be obtained (e.g., because the patient refuses to sign one), the provider must document its good faith efforts. Most importantly, the provider may use or disclose the patient's protected health information for treatment, payment and health care operations even if it does not obtain the patient's written acknowledgment. No special form of acknowledgement is required.

Incidental uses or disclosures of protected health information that occur in the course of authorized activity do not violate the Privacy Rule as long as the covered entity employs reasonable safeguards.

Under the Privacy Rule, covered entities must limit the amount of protected health information used or disclosed to the "minimum necessary" to carry out authorized activity. Health plans and providers have expressed concern that they would be deemed in violation of the Privacy Rule based on incidental disclosures such as overheard oral conversations that cannot reasonably be avoided.

The Final Amendment adheres to the Proposed Amendment by clarifying that incidental uses or disclosures that arise out of authorized activity, are limited in nature and cannot be reasonably prevented do not violate the Privacy Rule if the covered entity employs reasonable privacy safeguards. For example, patients do not need to be placed in private rooms to ensure that confidential conversations are not overheard; it would be sufficient to train staff to speak quietly and avoid discussing patient information in public settings whenever reasonably possible. Likewise, sign-in sheets at physician offices are not prohibited; however, the sign-in sheet should not contain medical information in addition to the patient's name. The intention of this clarification is to allow covered entities to engage in standard industry practices that are necessary for their efficient operation.

The minimum necessary standard does not apply to disclosures made pursuant to the patient's authorization.

Under the December 2000 Rule, while the minimum necessary standard did not apply to disclosures made for treatment or other specified purposes, it did apply to most disclosures made pursuant to an individual's authorization. The Final Amendment tracks the Proposed Amendment by exempting such disclosures from the minimum necessary requirement. This change will be particularly important to researchers and others who obtain protected health information as a result of authorizations.

Covered entities do not have to incorporate mandated language into contracts with business associates executed prior to October 15, 2002 until April 14, 2004 unless the contract is renewed or modified between these dates.

The Privacy Rule requires covered entities to incorporate certain mandated provisions into their contracts with all business associates. Under the December 2000 Rule, these provisions had to be in place by April 14, 2003, the Privacy Rule's compliance date.

The Final Amendment tracks the Proposed Amendment by establishing a one-year grandfathering period for a covered entity's contracts with business associates that are in effect as of the Final Amendment's effective date. Thus, contracts executed prior to October 15, 2002

do not have to contain the mandated business associate language until the earliest of (i) the date they are renewed, (ii) the date they are modified or (iii) April 14, 2004. The grandfathering does not apply to contracts entered into after October 15, 2002.

Covered entities may use model business associate contract language provided by HHS.

HHS has appended the same model business associate contract language to the Final Amendment as was attached to the Proposed Amendment. The model language gives covered entities alternative options for addressing many of the business associate requirements and serves as a useful starting point for drafting or amending business associate agreements.

Covered entities may not use or disclose protected health information for health-related marketing purposes without the individual's authorization.

Under the December 2000 Rule, a covered entity could not use or disclose protected health information for marketing purposes without the individual's written authorization unless the marketing (i) was face-to-face, (ii) involved products of nominal value or (iii) involved health-related products or services, in which case the covered entity had to satisfy certain requirements, such as providing the individual with an opt-out notice. This provision was subject to significant criticism from consumer groups because the "health-related products or services" exception gave covered entities substantial leeway to use protected health information for marketing purposes without obtaining the individual's prior approval.

The Final Amendment, like the Proposed Amendment, addresses these concerns by requiring the individual's authorization for all marketing uses and disclosures except those that are face-to-face or involve "promotional gifts of nominal value." The exception for "health-related products or services" is eliminated.

The definition of marketing excludes communications linked to treatment, case management and other similar activities but includes communications about the services or products of another entity for which the covered entity receives remuneration.

The Final Amendment tracks the Proposed Amendment by revising the definition of marketing contained in the December 2000 Rule in an effort to draw a clearer line between marketing and treatment-related education. Marketing is defined as "a communication about a product or service to encourage recipients of the communication to purchase or use the product or service." However, the Final Amendment tracks the Proposed Amendment by excluding from the definition of marketing communications that:

- Describe the type of products or services rendered by a provider or covered by a health plan. The Final Amendment makes it clear that descriptions of a health plan's provider network, communications about other benefit options not currently used by the enrollee or information about value-added, non-health care services offered by or through the health plan (e.g., membership in a health club) fall within this category.
- Relate to the treatment of the individual.

- Are for the purposes of case management, care coordination or the recommendation of alternative treatments, therapies, providers or settings of care.

In contrast to the December 2000 Rule, under the Final Amendment, the exceptions to the definition of marketing apply even if the covered entity receives compensation for such activities. If a covered entity receives compensation for activity that does not fall within one of the marketing exceptions, the authorization necessary to carry out such activity must state that the marketing may result in direct or indirect remuneration to the covered entity. In response to concerns expressed about potential abuses under the marketing definition in the Proposed Amendment, the Final Amendment contains a new provision stating that if a covered entity receives direct or indirect remuneration for disclosing protected health information to another entity for the purpose of enabling the other entity to sell its products or services, the disclosure constitutes marketing.

The status quo under state laws regarding the rights of parents and minors is preserved.

Although the Privacy Rule generally grants parents the right to serve as the personal representative of their children, it also defers to state laws restricting the disclosure of a child's protected health information to a parent. These laws, which often addresses matters such as HIV testing, family planning, abortion and other sensitive services, are deemed "more stringent" than the Privacy Rule and therefore are not pre-empted.

The Final Amendment mirrors the Proposed Amendment in seeking to clarify this principle. Among other things, the Final Amendment makes it clear that if state law is not prescriptive but is silent or gives health care providers discretion as to whether to disclose information about a minor to a parent, the Privacy Rule will not interfere with this discretion by either mandating or prohibiting disclosure. The Final Amendment also defers to state law in determining whether a parent who does not meet the definition of a personal representative has access to a child's protected health information.

An IRB or privacy board may apply simpler and more streamlined criteria when permitting use or disclosure of protected health information for research purposes without patient authorization.

Under the Privacy Rule, covered entities may not disclose protected health information for research purposes with patient authorization unless an Institutional Review Board ("IRB") or privacy board approves a waiver of the authorization requirement in accordance with a set of specified criteria. Research institutions complained that the criteria that had to be applied by an IRB or privacy board under the December 2000 Rule were too complex and confusing, making it difficult for waiver authorizations to be granted and impeding important research projects.

The Final Amendment tracks the Proposed Amendment by simplifying the waiver criteria and making them easier to integrate into the waiver process of the Common Rule, which governs

federally-funded research. Under the Final Amendment, an IRB or privacy board must consider the following criteria in determining whether to waive authorization:

- Whether the use or disclosure involves no more than a minimal risk to the privacy of individuals;
- Whether the research could practicably be conducted without the waiver; and
- Whether the research could practicably be conducted without access to and use of protected health information.

Researchers do not need to obtain special authorizations for research conducted in conjunction with treatment.

Under the December 2000 Rule, if individual authorization was required for research being conducted in conjunction with treatment, the authorization form had to contain special research-specific elements. Researchers complained that including these elements was burdensome and confusing.

The Final Amendment, like the Proposed Amendment, eliminates this requirement by establishing a single set of mandated provisions that must be included in all authorizations, including those involving research conducted in conjunction with treatment. These mandated provisions are described below. In addition, the Final Amendment, in contrast to the December 2000 Rule, allows an authorization for research to be combined with other research-related documents such as an informed consent.

The same transition procedures apply without regard to whether the research includes treatment.

The December 2000 Rule contained complex transition procedures that differed depending on whether research that began prior to the Privacy Rule's compliance date involved treatment (e.g., clinical trials) or was unconnected to treatment. Researchers objected to these provisions as burdensome and confusing.

The Final Amendment adheres to the Proposed Amendment and eliminates the distinction between the two types of research with regard to transition requirements. A covered entity may use or disclose protected health information created or received before or after the Privacy Rule's compliance date if, prior to the compliance date, the covered entity obtained (i) the individual's authorization, (ii) the individual's informed consent or (iii) an IRB waiver in accordance with the Common Rule or FDA regulations. These criteria apply without regard to whether the research had begun on the compliance date.

Covered entities may use and disclose a "limited data set" of protected health information for research, health care operations and public health activities without meeting the HIPAA test for de-identification.

Under the December 2000 Rule, covered entities could treat protected health information as de-identified only if 19 specified identifiers were stripped from the information or a qualified

statistician certified that the risk of identifying individuals from the information was small. In the Proposed Amendment, HHS solicited comments as to whether covered entities should be allowed to use and disclose a broader range of partially de-identified data for research and other limited purposes without the individual's authorization.

The Final Amendment adopts the approach suggested in the Proposed Amendment by allowing covered entities to use or disclose a "limited data set," which has fewer identifiers removed than is required to meet the de-identification test, if the data is being used or disclosed for research, health care operations or public health activities. The limited data set may be used or disclosed by a covered entity for these three purposes without the individual's authorization. Disclosures of a limited data set are not subject to the Privacy Rule's accounting requirement.

In order to constitute a limited data set, data may not contain certain facial identifiers such as name, street address and telephone number. However, in contrast to the Privacy Rule's requirements for de-identification, identifiers that are important for conducting research such as birth dates, treatment dates and zip codes do not have to be removed from the data.

When using or disclosing a limited data set, a covered entity must enter into a data use agreement with the party receiving the information. If the data is disclosed to an outside entity, the agreement will generally take the form of a formal contract or memorandum of understanding. If the data is used internally by members of the covered entity's staff, a confidentiality agreement signed by the employee should suffice. The elements that must be included in the data use agreement are similar to those required for business associate contracts.

Authorization forms may contain a simpler set of core elements.

The Privacy Rule requires covered entities to obtain an individual's written authorization for any use or disclosure of protected health information not otherwise required or permitted thereunder. Members of the health care industry complained that the December 2000 Rule's requirements regarding the content of authorization forms were cumbersome and confusing.

The Final Amendment, like the Proposed Amendment, seeks to address this problem by delineating a set of core elements that must be included in all authorization forms. These elements are:

- A specific description of the information to be used or disclosed;
- A description of the persons or class of persons authorized to use or disclose the information;
- A description of the persons or class of persons that may use or to whom the covered entity may disclose the information;
- A description of the purpose of the use or disclosure;
- An expiration date or event; and

- The individual’s signature, and if the signature is by a personal representative, a description of the representative’s authority to act on behalf of the individual.

The authorization form must state that the individual has the right to revoke the authorization in writing. The form must also explain that, to the extent mandated by the Privacy Rule, the provision of benefits or treatment may not be conditioned upon signing the authorization. Finally, the form must advise the individual that, once disclosed, information may be subject to redisclosure by third parties.

Authorization forms for research may specify “none” as the expiration date or event.

As indicated above, authorization forms must generally specify an expiration date or event. However, in response to concerns expressed by researchers, the Final Amendment allows an authorization form used for research purposes to state “none” as the expiration date or event. Covered entities may take this approach if protected health information is being incorporated into a permanent research database or repository, or if there is some other reason why it is not practical for the authorization to be time-limited.

The Final Amendment clarifies the terms of the Privacy Rule in several other respects.

The Final Amendment, like the Proposed Amendment, makes several minor changes to the Privacy Rule to eliminate ambiguities and address issues of concern raised by the health care industry. These corrections include the following:

- Specifying that protected health information may be transferred to another covered entity upon the sale, transfer, merger or acquisition of a business as part of the covered entity’s health care operations;
- Excluding from the accounting requirement any disclosures made pursuant to an individual’s authorization;
- Clarifying the circumstances under which covered entities may disclose protected health information to private entities acting on behalf of the FDA;
- Confirming that health plans may disclose enrollment or disenrollment information to the health plan’s sponsor (e.g., the employer) without requiring the sponsor to amend its plan documents as otherwise required to facilitate the receipt of protected health information.
- Clarifying that employment records held by a covered entity do not constitute protected health information.
- Permitting any entity providing a combination of health care and non-health care services to declare itself a “hybrid entity” even if its non-health care services are not its primary services. Hybrid entities may exempt their non-health care components from the Privacy Rule’s requirements.