

In an effort to respond to the concerns expressed by the healthcare industry to the privacy regulations that correspond to the Health Insurance Portability and Accountability Act, the Department of Health and Human Services issued proposed changes to the privacy regulations (the "Privacy Rule" or the "Rule"), in an effort to clarify certain provisions of the Rule which had sparked controversy in the healthcare industry as well as among advocacy groups and other public interest organizations.

Some groups were concerned, for example, about the requirement that a patient sign a consent form in order for a healthcare provider to use and/or disclose protected health information for treatment, payment and healthcare operations. Many in the industry worry that this requirement would be an obstacle to individuals seeking medical attention. Similarly, the Rule currently requires that healthcare providers use and disclose the minimum amount of health information necessary to accomplish the intended purpose of the disclosure. With respect to internal uses of such information, particularly in the context of oral communications, many concerns had been expressed regarding the potential negative effects on patient care.

Responding to comments such as these, HHS issued the proposed changes to the Privacy Rule on March 21, 2002 (the "Proposed Amendments"). The final version of such changes is anticipated to be released in October of this year. Among the most important modifications proposed, and clarifications made, by the HHS proposal are:

THE PROPOSED AMENDMENTS

A) Use and Disclosure

1. Consent and Notice Requirements: Among the most notable changes contemplated is the

repeal of the consent requirement, making the procurement of a consent form optional. If passed, healthcare providers with a direct treatment relationship (i.e. those who have direct control over the patient's care) would no longer be required to obtain an individual's consent prior to using and/or disclosing their protected health information for treatment, payment and healthcare operations. However, if a healthcare provider elects to obtain a consent, such consent may extend only to uses and/or disclosures permitted under the Privacy Rule.

In an effort to balance the lack of a consent requirement, a more stringent notice requirement has been proposed. The new notice requirement would obligate healthcare providers with a direct treatment relationship to make a good faith effort to obtain an individual's written acknowledgment that he/she had received the provider's notice of privacy practices at the time of the first service delivery.

2. Authorization Requirement: The Proposed Amendments would simplify the authorization requirement by permitting covered entities to use a single type of authorization form to obtain an individual's permission for a use and/or disclosure that is not otherwise permitted under the Privacy Rule. As proposed, this change includes the elimination of the specifications presently required for certain authorizations such as those for research that includes treatment.

3. Minimum Necessary Rule and Oral Communications: The Proposed Amendments would continue the minimum necessary rule's applicability to oral communications while clarifying that healthcare providers can verbally discuss a patient's treatment with other

providers involved in that patient's care without having to be concerned that they may have violated the Privacy Rule if the conversation is overheard.

Furthermore, the Proposed Amendments would make the minimum necessary rule inapplicable to all uses and/or disclosures made by a covered entity pursuant to a valid authorization. This change would conform to the proposal regarding authorizations mentioned above.

4. Marketing Communications: In an effort to simplify the marketing requirements, the Proposed Amendments would require covered entities to first obtain an individual's authorization before using or disclosing protected health information for marketing purposes except for i) face-to-face communications, or ii) promotional gifts of nominal value provided by the covered entity. Also, if any remuneration to the covered entity is expected, this must be disclosed in the authorization. The disclosure and opt out conditions in the Privacy Rule which, once satisfied, presently allow certain marketing communications to be made, would no longer be applicable.

5. Use and/or Disclosure for Research Purposes: The Privacy Rule presently requires researchers to secure multiple types of legal permission. The Proposed Amendments eliminate this requirement and would allow researchers to use a single form that combines both the provisions relating to informed consent and those relating more generally to the research participant's rights under the Privacy Rule.

Additionally, the Proposed Amendments would remove the distinction between the protected health information that may be released for research that includes treatment and research that does not include treatment. Consequently, the transition provisions of the Privacy Rule would be streamlined. In short, covered entities will be able to use and/or disclose protected health information for a particular research project that commenced prior to the compliance

date of the Privacy Rule. They will also be able to use the protected health information that was created or received both prior to, and following, the compliance date of the Privacy Rule using the legal permission that was obtained at the time the research commenced. Moreover, in accordance with the Common Rule, the Proposed Amendments will permit protected health information created or received pursuant to a waiver from an Institutional Review Board, or an informed consent prior to the compliance date, to be used for such research projects as well.

6. Parental Access: The Proposed Amendments clarify issues on the disclosure of a minor's protected health information to the minor's parent. Such disclosures are typically governed by state law. However, if the state law is uncertain or silent on such disclosure, healthcare providers may use their discretion as to whether to permit or deny a parent access to the minor's information as long as the decision made is in accord with the applicable law. Likewise, the same criterion is applicable to determinations of whether a personal representative of a minor can obtain the same access.

7. De-Identification of Protected Health Information: As a result of the currently cumbersome requirements for de-identification of protected health information, HHS has invited further comments on how to improve upon these requirements without disrupting the rigorous privacy protections presently in place. However, HHS is not seeking to replace the de-identification requirements, but instead is seeking to establish a "limited data set" that excludes directly identifiable information but still maintains certain identifiers. In order to safeguard information contained in a limited data set, covered entities that choose to disclose such information would need to obtain from the recipient an agreement: i) to limit the use of the information to its intended purpose and ii) not re-identify the information or use it in any way to contact the subject of the information.

B) Business Associates

Currently the effective date of the Privacy Rule is April 14, 2003, or April 14, 2004, for small health plans (i.e. those with five million dollars or less in annual receipts). The Proposed Amendments would provide covered entities, other than small health plans, with up to an additional year to amend their existing contracts or other written agreements with their business associates as long as those contracts were in effect as of the compliance date applicable to the covered entity. Moreover, the Proposed Amendments include a model business associate agreement provisions drafted by HHS.

C) Applicability of the Privacy Rule

Hybrid Entities: If passed, the Proposed Amendments will redefine hybrid entities, which are currently defined in the Rule as single legal entities that perform both covered and non-covered functions under the Privacy Rule, but the covered functions are not its primary functions. The amendment would remove the requirement that a hybrid entity must be an entity whose primary function is not a covered function. Instead, in order to be classified as a hybrid entity, the entity would be required to designate those components that would otherwise meet the definition of a covered entity. These components would be considered covered by the Rule and only these components, rather than the entire entity, would be required to comply with the Rule.

D) Individual Rights

Accounting of Disclosures: The Privacy Rule grants individuals the right to obtain accountings of the disclosures of their protected health information made by a covered entity. Currently, covered entities are required to account for all disclosures of an individual's protected health information, subject to a few exceptions. The Proposed Amendments add another exception for all uses and/or disclosures made pursuant to a written authorization from the subject of the information. Under the proposal, such disclosures would no longer need to be accounted for by the covered entity making the disclosure(s).

By addressing concerns expressed by those in the healthcare community, HHS has tried to improve the Privacy Rule and to resolve a number of the unintended consequences that the Rule's current form may create. HHS has stated that its aim is to further promote the efficient provision of quality healthcare to individuals by covered entities while also ensuring the privacy of the individual's health information. For additional information on the HIPAA Privacy Rule or the Proposed Amendments, visit the HHS website at <http://www.hhs.gov/ocr/hipaa/>.

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