

On Aug. 14, 2002, the Department of Health and Human Services published final modifications to the privacy regulations of the Health Insurance Portability and Accountability Act of 1996. The amendments contained in the Final Modifications make important changes to the HIPAA Privacy Rule, for which compliance is required by April 14, 2003 for most entities covered.

HHS issued the Final Modifications to address what it had termed the "serious unintended consequences of the rule that would have interfered with patients' access to quality care."

There were some changes worth noting, including:

Use and Disclosure

1. Consent and Notice Requirements: Perhaps the most notable change from the Privacy Rule is the abandonment of the consent requirement for the use and/or disclosure of protected health information for treatment, payment and healthcare operations. Providers with a direct treatment relationship with their patients are no longer obligated to obtain consent. Covered entities may still choose to obtain consent from such patients and are free to use whatever form they wish. As a result of this modification, all covered entities may use and/or disclose protected health information for the following functions without obtaining consent:

- For their own treatment, payment, or healthcare operations.
- For treatment activities of a provider.
- To another covered entity or provider for the payment activities of the entity that receives the information.

- To another covered entity for healthcare operations activities of the entity that receives the information as long as each entity has either had a relationship with the subject individual, the protected health information relates to such relationship, and the disclosure is for one of the purposes specified or for the detection of, or compliance with, law(s) related to healthcare fraud and abuse.
- To any other covered entity that participates in an organized healthcare arrangement with the disclosing entity for the healthcare operations of the organized healthcare arrangement.

While the consent requirement has been eliminated, the final modifications strengthened the notice requirement of the Privacy Rule.

Providers with a direct treatment relationship with their patients must now make reasonable efforts to obtain a signed acknowledgement from the patient that the patient has in fact received the provider's notice of privacy practices prior to the first service delivery.

In emergency situations, acknowledgement must be obtained as soon as is reasonable after the emergency has ended. If, after a good faith effort to obtain a written acknowledgement, the provider has not been successful, the provider must document the efforts made to obtain such acknowledgment and the reason why it was not obtained.

2. Authorization Requirement: The authorization requirement under the Privacy Rule has been simplified in the Final Modifications. The requirement to obtain different authorizations depending on the use and/or disclosure anticipated has been deleted. Patients will still have to grant

permission in advance for those disclosures requiring an authorization, but providers will not need to use different types of forms each time.

3. Minimum Necessary Rule and Incidental Use and Disclosure: The Privacy Rule previously exempted only specific types of authorization from the minimum necessary requirement, but since the Privacy Rule now requires only a single authorization, the exemption is applied to that authorization.

Another major concern addressed by the Final Modifications relates to oral communications and incidental disclosures. Covered entities will not be held liable for incidental disclosures made pursuant to an otherwise authorized use and/or disclosure as long as the entity takes reasonable measures to safeguard the information from such incidental uses or disclosures.

4. Marketing Communications: The marketing communication requirements have become more restrictive. The Final Modifications require a covered entity to get an individual's prior written authorization to use protected health information for marketing purposes except for a face-to-face encounter or a communication involving a promotional gift of nominal value.

This change eliminates the ability of covered entities to use the old opt-out provisions of the Rule to make marketing communications without an authorization.

In addition, a single authorization form is now generally applicable to all uses or disclosures requiring authorization. But if the authorization is being obtained for marketing purposes and the covered entity will be paid for it, the authorization form must so specify. This statement is the only required provision of an authorization that is specific to a particular disclosure and therefore must be inserted in an entity's general authorization form.

The Final Modifications also emphasize that it is impermissible under the Privacy Rule for covered entities to sell patient or enrollee lists to third

parties. Likewise, covered entities must obtain an individual's authorization prior to disclosing any protected health information about the subject individual to a third party for its marketing activities.

While overall the Final Modifications made the marketing requirements more stringent, they did ease the burden on health plans with regard to their own products, benefits or services. As a result, health plans can advise their members about available coverage and the like without violating the Privacy Rule's marketing requirements.

5. Use and/or Disclosure for Research Purposes: The Final Modifications allow researchers to use a single permission 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, if the researcher obtains legal permission to use or disclose protected health information prior to the compliance date, that legal permission will continue to apply to such information even after the compliance date.

The Final Modifications are now more congruous with the Common Rule in that the Final Modifications allow protected health information created or received pursuant to a waiver from an Institutional Review Board, or an informed consent issued prior to the compliance date, to be used for such research projects as well.

6. Parental Access: The Final Modifications clarify the parental access provisions of the Privacy Rule.

A covered entity may disclose protected health information about an unemancipated minor to the parents, guardian or other person acting in loco parentis if the disclosure is permissible under state law. Likewise, a covered entity cannot disclose such information if prohibited by state laws.

In cases where a minor controls her health information and state law doesn't address a parent's ability to access such information, a covered entity may exercise its professional judgment so long as its decision is not inconsistent with applicable law.

7. De-Identification of Protected Health

Information: The Final Modifications clarify if a covered entity assigns codes to de-identified data in order to re-identify it later, such codes are not considered individual identifiers under the Privacy Rule.

8. Disclosing Enrollment Information to a Plan

Sponsor: The Final Modifications to the Privacy Rule now permit self insured group health plans, or a health insurance issuer or HMO for a fully-insured health plan, to disclose information regarding whether an individual is participating in the group health plan, or is enrolled in or is disenrolled from a health insurance issuer or HMO offered by the plan to the plan sponsor without amending the plan documents.

9. Limited Data Sets: As proposed, the Final Modifications include the introduction of the "limited data set" for research, public health purposes, and healthcare operations. A limited data set is a concept similar to de-identified information in that a limited data set contains protected health information that has had a number of specified identifiers removed. These identifiers include a number of those required to be removed for de-identified information as well. However, unlike de-identified information, not all of these identifiers need to be removed in order to constitute a limited data set.

Covered entities may create and disclose a limited data set if the covered entity enters into a data use agreement with the recipient of the information. Information disclosed in a limited data set can be used only for the purposes of public health, research or healthcare operations.

A data use agreement is similar to a business associate agreement in that it requires the recipient of the information to agree, among other things, to limit the use of the information for the purposes specified, use appropriate safeguards to protect the information, report unauthorized uses to the entity disclosing the situation, and refrain from identifying the information or contacting the individuals who are the subject of the information.

Business Associates

In the Final Modifications, covered entities, other than small health plans, are now given up to an additional year to amend their existing contracts or other written agreements with their business associates. Contracts that were in effect as of the compliance date applicable to the covered entity do not need to be modified until the contract is up for renewal or April 14, 2004, whichever is earlier.

This additional compliance period, however, is not available where the covered entity does not have a written contract with a vendor. In this situation, the covered entity must have a business associate agreement in place by April 14, 2003.

In addition, any contract that is renewed or modified prior to October 15, 2002 must comply with the business associate standards by April 14, 2003. HHS has issued sample business associate agreement provisions that can be used as guidance in drafting business associate agreements.

Applicability of the Privacy Rule

The definition of a "hybrid entity" has changed slightly but this small change could have profound effects on an entity that meets the definition. The Final Modifications removed the requirement that to be a hybrid entity the organization's primary function must be something other than healthcare. Now the primary function of an organization does not play a role in determining the organization's status as hybrid entity.

The Final Modifications also state that a covered entity is not a hybrid entity simply because it is the plan sponsor of a group health plan. HHS states that the plan sponsor and the health plan are separate legal entities and therefore do not qualify as a hybrid entity. A hybrid entity is a legal entity that constitutes a covered entity under the Privacy Rule and whose business is comprised of both covered and non-covered functions and that "designates" healthcare components.

Individual Rights

Covered entities no longer need to account for

disclosures of protected health information made pursuant to a valid authorization. Protected health information released as part of a limited data set also does not need to be accounted for.

With respect to disclosures made for research purposes, the accounting that must be provided to an individual has been simplified. Such accountings only need to disclose the name of the project, a description of the research for which the disclosure was made and certain dates and contact information.

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