

LEGAL ALERT

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HEALTH CARE LAW UPDATE UPDATE ON HIPAA PRIVACY AND TRANSACTIONS STANDARDS

PROPOSED CHANGES TO THE PRIVACY STANDARDS: WHAT'S THE BOTTOM LINE?

By Veronica A. Marsich, J.D.

By now everyone in health care is aware that on March 21, 2002, the Department of Health and Human Services issued a collection of proposed revisions to the ever burdensome, much maligned "HIPAA - Privacy Standards."

Now that these proposed changes have been published in several forms and formats, dissection of the proposed changes is underway. Our own review of the changes has led us to conclude that: (1) the changes proposed by HHS are consistent with the Privacy Standards Guidance issued by HHS on July 6 of 2001; and (2) if adopted in their current form, the proposed changes would, by and large, benefit the health care provider community in its efforts to achieve HIPAA compliance.

Some of the most significant of the proposed changes to the Privacy Standards can be summarized as follows:

CONSENTS

Treatment, payment and certain health care operations ("TPO") are at the core of what health care providers do and the requirement to obtain written consent from a patient in order to carry out most TPO functions was a tremendous burden in the Privacy Standards. HHS appears to have heard the provider communities' cry for relief from this burden and proposes to completely do away with the HIPAA consent requirement.

Instead, HHS proposed to make the decision to obtain written consent a purely optional one and to emphasize the Notice of Privacy Practices as the method for communicating with patients about how health care providers use or disclose their health information for TPO purposes.

As a trade-off for eliminating the consent requirement,

however, HHS indicates in the proposed rule an intention to strictly enforce requirements for obtaining an individual's authorization for uses or disclosures of PHI not otherwise permitted. This means that health care providers will still need to make sure, when performing their assessments and developing their HIPAA compliance policies that they clearly understand those activities that will and will not be included in the definition of TPO and that if an activity is not clearly TPO, providers get a clear opinion or determination regarding whether an authorization for use or disclosure is necessary.

AUTHORIZATIONS

In addition, HHS has clarified that, despite the language in the Final Rule, it did not intend health care providers to be limited in sharing information with other health care providers for treatment and payment

purposes. So, in order to fix this unintended consequence of the regulations, HHS proposes to revise the Privacy Standards to specifically state that an authorization is not required for health care providers to share information for the "treatment" and "payment" purpose of another covered entity or health care provider.

Similarly, with respect to health care operations, HHS proposes to eliminate any authorization requirement for the disclosure of health care operations related to matters like quality improvement, case management, training programs, accreditation, certification, licensing activities of other covered entities, which have or have had a relationship with the individual who is the subject of the information.

Obviously, this proposed revision relative to health care operations is more limited than revisions for treatment and payment. Importantly, HHS has emphasized that even if an authorization is not required, for payment or certain health care operations, concepts of minimum necessary will still apply to those uses and disclosures. Therefore, this will still be an area where providers will need to devote time and attention during their HIPAA assessments and policy development.

The proposed amendments also eliminate the requirement to use a different form when the

covered entity requests an authorization. A single form will be sufficient whether the authorization is for the individual's or covered entity's purposes.

NOTICE OF PRIVACY PRACTICES

HHS proposes that all health care providers having a direct treatment relationship with an individual will need to make a good faith effort to get "acknowledgements" from patients at the time the Notice of Privacy Practices is distributed. The goal here appears to be to emphasize the Notice of Privacy Practices in the minds of patients by forcing providers to try to get acknowledgments by patients that received the Notice.

Many issues exist relative to this proposed emphasis on the Notice and new "acknowledgment" requirement, however. For example" what will constitute a "good faith effort" on the part of health care providers relative to obtaining acknowledgement from a patient and how will providers prove their good faith effort? What must be contained in the acknowledgement itself? And given that HHS will not require that providers get a patient's signature on an acknowledgement "form," how will providers provide their compliance with these new requirements? We expect that these along with other issues

surrounding the Notice and this new Acknowledgement will be clarified if and when these proposed changes to the Privacy Standards are published in final form.

MINIMUM NECESSARY REQUIREMENT

With regard to the requirements for minimum necessary disclosure set forth in the Privacy Standards, HHS proposes to clarify that in instances where a covered entity obtains a valid authorization, there would be no need for the provider to worry about the "minimum necessary" requirements. However, despite this proposed clarification, HHS comments in the proposed changes make clear that providers will still need to develop policies and procedures ensuring compliance with the minimum necessary standards in all other settings and that even in a treatment context, it will be wise for providers to be mindful of "minimum necessary" concepts.

BUSINESS ASSOCIATES

To the extent covered entities have contracts with individuals or entities who will constitute "business associates" as that concept is defined in the Final Rule, HHS proposes that if those contracts are not set to expire or be renewed prior to the effective date of the final rule, April 14, 2003, covered entities may have an extension

of up to 12 months to implement business associate agreements with those parties. This extension should enable providers to, in an orderly fashion, modify existing contractual arrangements with business associates to account for the requirements set forth in the Final Rule. Importantly, this extension will not apply to arrangements that providers have failed to previously memorialize in writing.

MARKETING

In perhaps the only area of the proposed changes where HHS appears to have taken a more stringent approach than the current rule, the proposed modifications to the Privacy Standards provide that any communications defined as “marketing” under the Regulations will require authorization from the patient. If implemented, covered entities will no longer be able to make any type of marketing communications, even those made on their own behalf and for their own services, without authorization. Under the

proposed rule, HHS also proposes to alter the definition of “marketing” to ensure that if the effect of the communication is to encourage patients to purchase or use the product or service, the communication is considered “marketing”, regardless of the intent.

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While there are several other clarifications that HHS proposes to make to the Privacy Regulations, the above represent some of the most significant changes and those that are of greatest interest to covered entities as they move forward with their assessments and policy development.

It is clear from the comments and commentary from politicians, the press and those within the health care industry that the changes to the Privacy Standards proposed by HHS have become a political as well as a legitimate privacy issue. Whether, when and to what extent these or any other changes will actually be made to the HIPAA Privacy Standards

before their effective date is still anyone’s guess. While many of these changes, such as the marketing change and the extension of time to sign business associate agreements seem like relatively benign issues, the elimination of the consent requirement is likely to be the subject of tremendous debate. Senator Kennedy has vowed to legislatively defeat any proposal to eliminate the consent requirement.

Given this uncertainty, we recommend that health care providers continue to move forward with their HIPAA assessments and other compliance efforts, focusing on those things we know will not change: the need for policies and procedures on privacy, the need to have a Notice of Privacy Practices and to understand what your privacy practices are, etc. Further guidance on these issues and areas of uncertainty will be forthcoming as we get closer to the mandatory date for compliance.

MODEL FORM FOR EXTENSION OF ELECTRONIC TRANSACTIONS STANDARDS IS AVAILABLE

By: Richard C. Kraus

Under a statute enacted last December, a covered entity may obtain an extension of the deadline for complying with the HIPAA Standards for Electronic Transactions and Code Sets until October 16, 2003. In order to be eligible

for the extension, a covered entity must submit a summary of its current compliance status and planned implementation strategy to HHS. SHRR’s Legal Alert discussing the extension is available by clicking [here](#). You may also find this and other

Legal Alerts on the Smith Haughey web site at http://www.shrr.com/resources/legal_alerts.cfm

HHS has now published the form that must be submitted. The form and instructions are available at www.cms.hhs.gov/hipaa/hipaa2/default.asp

We will send you a copy if you prefer.

Electronic submission of the form will be available on HHS's web site in the near future. The form can also be mailed to:

ATTENTION: Model Compliance Plans
Centers for Medicare & Medicaid Services
P.O. Box 8040
Baltimore, MD 21244-8040

Completed forms must be electronically submitted or postmarked by October 15, 2002.

Although HHS indicates that completing the form will only take a few minutes, gathering the necessary information will require an assessment of current progress on complying with the standards and development of an implementation strategy. In many cases, providers will need to determine the compliance efforts of any trading partners such as vendors, contractors and clearinghouses and coordinate implementation efforts, testing schedules, and data migration processes. We recommend that you obtain and review a copy of the form and instructions so that you will be ready to file the extension request by October 15.

HIPAA PRIVACY & SECURITY STANDARDS:

A RESOURCE FOR INITIAL ASSESSMENT AND IMPLEMENTATION

The HIPAA Project Team has created a comprehensive binder and CD-ROM resource for conducting an initial review of HIPAA compliance and starting a compliance program. For ordering information, contact Wendy Passineau, Client Services Director, at 616.458.3636 or wpassineau@shrr.com

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