HEALTH INFORMATION TECHNOLOGY ADVISORY

HIPAA UPDATE

Spring 2002

Basic HIPAA Implementation Facts

- HIPAA is not going away.
- If you, or any part of your organization, provide health care services (or prescription drugs or products) and you do any electronic billing, you are a HIPAA "covered entity."
- The three major components of HIPAA (electronic transactions and code sets, privacy and security) have separate requirements and compliance deadlines. Only one deadline (electronic transactions and code sets) has been extended for entities filing a compliance plan.
- Significant parts of HIPAA will require substantial lead time to implement.
- Some important details of HIPAA remain a moving target. Changes are proposed in the privacy regulations and some specifications for electronic transactions standards may change as well.
- Proposed modifications to the privacy regulations should not delay implementation efforts.
- By now, your HIPAA implementation strategies should be defined, budgeted and under way.

This Advisory will update you on each HIPAA component and direct you to resources for further details and assistance.

Wiggin & Dana LLP Counsellors at Law

New Haven Hartford Stamford Philadelphia

www.healthIT.info www.HIPAA-law.info www.wiggin.com Wiggin & Dana has prepared a detailed analysis of how the recently proposed modifications to the privacy regulations could affect the numerous implementation tasks involved in complying with the regulations. This chart is available on our HIPAA web page, www.HIPAA-law.info, or by contacting any member of our HIPAA Team.

Overview

Although several aspects of HIPAA remain subject to some modifications, any provider or organization covered by these extensive requirements should be tracking them closely and should now have HIPAA compliance strategies identified and in progress. The three separate components to the health information or "Administrative Simplification" requirements of HIPAA (the Health Insurance Portability and Accountability Act of 1996) are: (a) electronic transactions and code sets requirements; (b) privacy and (c) security. For our detailed summary of the HIPAA statute and regulations, including recent proposed modifications to the privacy regulations, please see "HIPAA: Privacy, Security, Electronic Transactions—Summary of Statute and Regulations" on Wiggin & Dana's HIPAA web page at www.HIPAA-law.info.

As discussed below, there are two recent HIPAA developments of major significance. First, at the request of Congress, HHS has published instructions enabling covered

entities (except small health plans) to extend their compliance date for the electronic transactions and code sets regulations until October 16, 2003 by filing a compliance plan no later than October 15, 2002. Secondly, as promised, HHS has proposed modifications to the HIPAA privacy regulations. If adopted, these changes would remove the current requirement for obtaining "consent" before using or disclosing health information for treatment, payment or health care operations. As described below, the modifications would change other details of HIPAA privacy, but would not generally impact the structure or substance of these comprehensive requirements concerning use and disclosure of health information. There is no proposal to extend the April 14, 2003 HIPAA privacy compliance date. Although final HHS actions on these proposed modifications will take several more months, HIPAA privacy implementation can and should be moving forward according to a well organized and sequenced implementation plan.

Electronic Transactions and Code Sets Requirements

File Compliance Plan by October 15, 2002 to Extend Compliance Deadline

These regulations and associated implementation guides establish standards for certain electronic transactions, such as electronic billing, and data elements for these transactions to standardize the electronic exchange of health information. (The final electronic transactions and code set requirements and implementation guides are available at www.aspe.hhs.gov/admnsimp/bannertx.htm.) Compliance with these requirements generally involves coordination with one or more software vendors and then testing compliance capability. The original compliance deadline is October 16, 2002 (except for small health plans). However, Congress recently extended that compliance date to October 16, 2003 if the covered entity submits a compliance plan to the Department of Health and Human Services (HHS) by October 15, 2002. In the Administrative Simplification and Compliance Act ("ASCA") of December 2001, Congress authorized HHS to exclude from Medicare any covered entity that does not either file a compliance plan or become compliant with the electronic transactions and code sets requirements by October 16, 2002. HHS has issued a model compliance plan and associated instructions, which are available on the HHS HIPAA web site at www.cms.hhs.gov/hipaa. Although use of the HHS model plan is optional, it is simple and straightforward. Completing the HHS form ensures that you have satisfied the requirements for filing a compliance plan. The plan may be filed electronically or on paper. In the plan, the covered

entity must address the reason for the extension request, the work plan for achieving compliance and plans to begin testing by April 16, 2003.

Most providers will need to obtain the extension of this compliance deadline. Many vendors will not be prepared to meet the original 2002 deadline. Since most large payor organizations will not be ready, testing would be extremely difficult this year. In addition, there may be changes during the year to some of the standards. And there is no disadvantage to filing for the extension.

Your compliance efforts now for the electronic transactions and code sets requirements should include:

- Obtain and review HHS model compliance plan form and instructions.
- Determine which covered electronic transactions are performed by your organization.
- Work with your software vendors to be certain that they will upgrade your systems as needed for compliance and to determine timetable.
- Identify any additional data elements that must be collected in order to comply with applicable standards.

New Haven 203,498,4400 Hartford 860.297,3700 Stamford 203,363,7600 Philadelphia 610-727-4153

Privacy Requirements

Your HIPAA Privacy Compliance Strategy Should Be Defined, Budgeted and Under Way

When extending the compliance deadline for the electronic transactions and code sets regulations, Congress specifically stated that it was not extending the April 14, 2003 compliance date for the privacy regulations. Privacy generally is the most expansive of the HIPAA requirements and has caused the most discussion and concern. (The original final privacy regulations are available at www.hhs.gov/ocr/hipaa/finalreg.html.) Implementing the HIPAA privacy requirements necessitates reviewing and revising practices for use and disclosure of information throughout the organization; contracting with "business associates" who receive or may access protected health information; adopting numerous new policies and procedures required by HIPAA; educating the workforce on these new requirements and establishing mechanisms to assure ongoing compliance.

In response to the many questions and issues raised after the final privacy rule took effect, HHS issued Guidance in July of 2001. (Available at www.hhs.gov/ocr/hipaa/assist. html.) The HHS Guidance clarified several questions, and indicated that some issues would require modification of the regulations. On March 27, 2002, HHS issued a Notice of Proposed Rulemaking proposing several modifications to the privacy rule and seeking comments. (Available at www.hhs.gov/ocr/hipaa/finalreg.html.)

The most significant change proposed is elimination of the requirement that covered health care providers obtain a patient's advance written consent to use or disclose protected health information for treatment, payment or health care operations. Instead, under the proposed modifications, the provider would be required to make a good faith effort to obtain an individual's written acknowledgement of receipt of the provider's notice of privacy practices. Removing the consent requirement would help alleviate logistical problems raised by requiring a consent in advance of using health information, such as scheduling appointments, filling prescriptions, or evaluating potential new patients for a referral or admission.

The proposed modifications do not change the substance or structure of the Privacy Rule.

Neither the elimination of the consent requirement nor the other smaller proposed revisions would fundamentally change the substance or structure of the HIPAA privacy requirements. These proposed changes are generally helpful and serve to fine-tune some of the privacy regulations. They include proposed revisions affecting marketing, research, authorization forms and the designation of "hybrid" entities, among other smaller changes. The HHS proposal also asked for comments concerning an alternative approach to "de-identification," which would alleviate some problems regarding use of data for quality review and research.

The proposed modifications include a model business associate agreement. Use of this model is optional, however, and many covered entities will choose to include additional provisions for clarity and liability protection. The proposed modifications, if adopted, would also allow up to an additional year for covered entities to amend certain written agreements with business associates.

The proposed privacy modifications should NOT be considered a reason to delay implementation plans and activities.

HHS does not have the authority to delay the April 14, 2003 compliance deadline; only Congress can delay it, and there is no indication that Congress intends to do so. The very extensive nature of the tasks required to implement the privacy regulations – ranging from inventorying existing information practices, to establishing contracts with business associates, to developing numerous policies and procedures, to educating the entire workforce concerning these new policies and requirements – generally will require the full time now remaining before the compliance deadline.

We expect that HHS will finalize the proposed modifications to the privacy requirements by early fall, 2002. It is possible—and necessary – to proceed with privacy implementation by structuring and sequencing implementation tasks to minimize the need for revision once the proposed modifications are finalized. For this purpose, Wiggin & Dana has prepared a detailed analysis of the impact of the proposed modifications on the numerous implementation tasks involved in complying with the privacy regulations. This chart is available on our HIPAA web page www.HIPAA-law.info or through contacting any member of our HIPAA Team.

For further information concerning the privacy requirements, see the HIPAA Summary referenced above, or contact a member of our HIPAA Team.

Wiggin & Dana HIPAA Team

Jeanette C. Schreiber 203.498.4334 jschreiber@wiggin.com

Maureen Weaver 203.498.4384 mweaver@wiggin.com

Michelle Wilcox DeBarge 860.297.3702 mdebarge@wiggin.com

Catherine P. Baatz Michele B. Gerroir Mark W. Heaphy Stacie Kelly Jennifer N. Willcox

Health Care

Maureen Weaver, Chair 203.498.4384 mweaver@wiggin.com

Litigation

Shaun S. Sullivan, Chair 203.498.4315 ssullivan@wiggin.com

Business

William A. Perrone, Chair 203.363.7604 wperrone@wiggin.com

Intellectual Property

Mary R. Norris, Chair 203.498.4377 mnorris@wiggin.com

Employment and Benefits John G. Zandy, Chair

203.498.4330 jzandy@wiggin.com

Security Requirements

Understand the Proposed Requirements and Address Them Where Appropriate in Privacy Implementation

The HIPAA security regulations are still in proposed form, as originally published on August 12, 1998. (Available at www.aspe.hhs. gov/admnsimp/bannerps.htm#security.) These proposed regulations outline general HIPAA-required security measures, including administrative, physical and technical safeguards. It is generally believed that the final security regulations will be similar to the proposed regulations. Once finalized, there will be a two-year period in which to comply with these security requirements.

All organizations working on HIPAA privacy implementation should be familiar with the security requirements. For efficiency in implementation, procedures identifying information flow for privacy implementation should be designed to identify issues relating to security as well. Organizations contemplating the purchase of new computer systems or software should also be sensitive to these proposed requirements.

Wiggin & Dana HIPAA Services

Wiggin & Dana is presently working with a wide variety of organizations covered under HIPAA, as well as groups of organizations working on collaborative HIPAA implementation projects. We have structured our services to be flexible enough to provide as little or as much help as any one client may need. For example, we can help oversee an organization's entire compliance effort; we can develop

or review necessary forms, models, policies and procedures; we can provide educational programs; and/or we can provide support through trouble-shooting specific issues or problems. Pricing structures are also flexible. For a "menu" of our available HIPAA services, please see our HIPAA web page www.HIPAA-law.info or contact a member of our HIPAA team.

Nothing in this Health Information Technology Advisory constitutes legal advice, which can only be obtained as a result of personal consultation with an attorney. The information published here is believed to be accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.

Wiggin & Dana LLP One Century Tower P.O. Box 1832 New Haven, Connecticut 06508-1832