HHS Publishes Proposed Changes to the HIPAA Privacy Regulation… Where Do We Go From Here?

Detailed analyses and summaries of the proposed changes to the HIPAA privacy regulations have flooded the healthcare community by a multitude of national and trade media even before the proposal’s official publication in the March 27, 2002, Federal Register. The question to be addressed now is:

“What practical affect do these proposed changes have on the healthcare community?”

For the time being, the answer to that question is...

NONE!

To be sure, it is important to be aware of the proposed changes and, as part of the process, to submit comments on the proposal to the Department of Health and Human Services (DHHS) as appropriate. Other actions based on the proposed rule, would, at this point, be premature.

BACKGROUND

The 1996 Health Insurance Portability and Accountability Act (HIPAA) was an attempt at health care reform. There were several “topics” within the one
omnibus bill, including: 1) creating portability of insurance so that employees with pre-existing conditions did not experience “job-lock” based on needing health insurance; 2) creating standards for long term care insurance; 3) creating many new provisions designed to curb healthcare fraud and abuse; and 4) creating healthcare billing administrative simplification. It is administrative simplification that is now garnering most of the attention.

The goal of administrative simplification was to standardize the healthcare billing process to create a more efficient system that was less prone to mistakes and fraud. By standardizing transactions and using electronic data interchange to submit claims, claims could be submitted faster and more accurately. On the payor end, the claims would be easier to decipher and, ultimately, payments could be made more quickly.

Submitting healthcare claims electronically created concerns regarding patient privacy and confidentiality. HIPAA was enacted with a “place holder” provision that gave Congress until August 21, 1999, to come up with a legislative plan to protect patient privacy and confidentiality. If Congress did not enact any provisions, the DHHS would issue regulations. Since Congress did not act, DHHS did, and after issuing a proposed rule that generated 52,000 comments, published a final rule on December 28, 2000.

When President Bush assumed office, he ordered a review of rules published shortly before the Clinton presidency ended. He opted to not withdraw the privacy final rule, but allowed a new comment period. DHHS was subsequently directed to issue guidance documents to help the healthcare community implement the final rule. In its first guidance, DHHS announced that it would propose modifications to the privacy rule “to address problems arising from the unintended effects of the Privacy Rule on health care delivery and access.”

**THE PROPOSAL - THE HIGH POINTS**

Of course, the most noted proposed change relates to the consent requirements in the final rule. Interestingly, these requirements were not included in the original proposal, but were included in the final rule. The final rule required covered entities-defined as health plans, clearinghouses, and providers that transmit certain health information electronically-to obtain a patient’s consent before the patient’s protected health information could be disclosed for treatment, payment and healthcare operational purposes.

Now, DHHS appears to have decided that requiring covered entities to obtain the consent may not be necessary. Instead, the rule would state that entities could obtain consent if they so chose, but lack of consent would not impede the disclosure of protected health information for these limited purposes. In addition, the proscribed contents of the notice would be deleted. Finally, members of an organized health care arrangement (OHCA) would be able to disclose protected health information for health care operational purposes to other members of the OHCA without first obtaining consent. An OHCA is defined as, among other things: 1) a clinically integrated healthcare setting; 2) an organized system of health care with more than one covered entity participating that holds itself out as a joint arrangement participating in joint activities such as utilization review, quality assessment, or payment activities; or 3) group health plans maintained by the same plan sponsor.

Some of the reasons for this proposed turn-around were in response to concerns raised by pharmacies and pharmacists. The final rule would have hindered a pharmacist’s ability to fill prescriptions based on information from a physician without obtaining the patient’s consent. This illustrated the potential burden requiring a signed consent form could create.

Covered entities would still be required to obtain an authorization for any disclosure that is not related to treatment, payment, or healthcare operations. In fact, DHHS proposes to add “marketing” as a purpose for which an authorization would be required. Additionally, the proposal would increase the core elements and requirements of an authorization.

There had been a great deal of concern over the marketing processes a covered entity could employ pursuant to the final rule. The proposed rule would clarify what is and what is not considered “marketing” as it relates to health privacy. There were several circumstances identified in the final rule for which an authorization or opportunity to agree or object to a disclosure is not required. For example, an authorization was not required for uses and disclosures required by law or public health activities. The proposed rule would expand the permitted disclosures identified as public health activities to include actions under the jurisdiction of the Food and Drug Administration (FDA) such as tracking FDA-regulated products and conducting post-marketing surveillance.

Covered entities would still be required to issue a notice of their privacy practices; however, that notice would only need to describe those uses or disclosures of protected health information that may be made without the individual’s written authorization. Covered entities would be required to issue the notice no later than the first day healthcare services are provided past the April 14, 2003, compliance date. Alternatively, in an emergency situation, the notice would be required to be issued “as soon as reasonably practicable after the emergency.” Entities would be required to only “make a good faith effort to obtain a written acknowledgement of receipt of the notice” and to document any written acknowledgment or its good faith effort to obtain the acknowledgment.

The proposal would also exclude from the definition of “protected health
information” any “employment records held by a covered entity in its role as employer.” This means that any health information included in an employee’s record might not be protected.

Another major proposed change to the final rule involves the use of business associate contracts. Business associates are defined as entities that, while not having a treatment relationship with the patient per se, may need the information to support the covered entity’s healthcare operations. These entities furnish legal, actuarial, accounting, consulting, management, administrative accreditation, data aggregation, and financial services to covered entities. Because business associates are not employees of the covered entity and, thus, are not under the covered entity’s direct control, the final rule required providers to ensure that their business associates also maintain patient privacy. The rule required covered entities and their business associates to enter into contracts to ensure that the business associate was aware of, and adhered to, the covered entity’s privacy practices. The final rule listed the requisite elements of the contract.

There had been a great deal of concern about these contracts as well as the timing for obtaining them. To alleviate some of these concerns, DHHS included a model business associate contract in an Appendix to the Preamble of the proposed rule. In addition, the proposed rule would give covered entities up to one additional year to come into compliance with the business associate contract requirement. Basically, the proposed rule would require that the provisions of business associate contract be included in any contract that is renewed after April 14, 2003, but no later than April 14, 2004.

It should be noted that lack of a business associate contract does not relieve the covered entity of its liability if a business associate does not maintain patient privacy. In the Preamble, DHHS stated that:

[c]overed entities would still be required to fulfill individuals’ rights with respect to their protected health information, including information held by a business associate of the covered entity. Covered entities must ensure, in whatever manner effective, the appropriate cooperation by their business associates in meeting these requirements.

Thus, the delay in requiring business associate contracts is somewhat of a double-edged sword. Covered entities must find a way to ensure that their identified business associates respect the privacy requirements with or without a contract.

The proposal would also loosen up privacy restrictions to allow parents increased access to medical records of unemancipated minors, unless the increased access was contraindicated by state law.

One of the problems associated with creating federal privacy regulations by federal regulation and not by statute, is that federal regulations cannot supersede state law. Therefore, state privacy laws that are more stringent must be followed. This means that all members of the healthcare community must be versed in state law and recognize when state law supersedes the federal regulation. A proposed change in the federal privacy regulation would clarify that a state law is “more stringent” if the state law gives an individual “greater rights of access or amendment” to his or her individually identifiable health information.

WHAT’S NEXT?

Procedurally, comments on the proposed rule are due April 26, 2002. DHHS then has to compile all of the comments, determine whether the proposed changes should be retained, and issue a final rule. All of this must happen quickly to give the healthcare community time to “digest” and implement the new final rule before April 14, 2003. In fact, in the Preamble, DHHS stated that for the April 14, 2003, compliance date to remain feasible, any change to the final rule would be effective October 13, 2002. Thus, we can expect a final rule to be published before mid-Octoer.

Remember—small health plans—those with annual receipts of less than $5 million—still have until April 14, 2004, to be in compliance with the privacy regulations. The proposed changes would not affect the extended compliance deadline for these entities.

WHAT SHOULD THE HEALTHCARE COMMUNITY DO?

We are all in a tough spot right now. On the one hand, we must comply with the privacy regulation beginning April 14, 2003. It is, therefore, prudent to prepare for compliance. On the other hand, we know that changes will be made, but we just don’t know the extent of those changes. Still there are steps that can be taken:

• There were minimal proposed changes to the provision requiring the development of a notice of privacy practices. Begin drafting that notice now.
• There were no proposed changes to the provisions addressing the creation of an organized health care arrangement (OHCA). Take stock of the various providers with whom an arrangement would be more efficient with respect to patient care and begin formulating an OHCA.
• While the Business Associate contract may be delayed, somewhat, why wait? Identify your business associates, determine when contracts are being renewed, and begin drafting requisite provisions.
• Continue to sensitize your staff about the need to maintain patient privacy. Most of all—STAY CALM!! Most covered entities have long had policies in place to protect patient privacy. The goal
of this process is to ensure that everyone in the healthcare delivery system—patients, their families and providers—have the proper protections to ensure against surprises regarding their medical record. And, look to Holland & Hart to provide you with the support you need to manage this process calmly and reasonably.

The proposed rule is available from the Federal Register at:

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-7144-filed or from the DHHS web site:

http://www.hhs.gov/ocr/hipaa/whatsnew.html. Holland & Hart has created a redline version of the proposed rule illustrating the proposed additions and deletions. This can be found at:

www.hollandhart.com/articles/FinalPrivacyStandard.pdf

CMS Delivers… On Time!

As mandated by the Administrative Simplification Compliance Act (ASCA), the Centers for Medicare and Medicaid Services (CMS) released a model document that covered entities can use to request a one-year extension from the October 16, 2002, transaction standard and code set deadline. The document must be submitted by October 15, 2002. A group practice can submit one form on behalf of all its physicians unless a physician bills separately and outside of the group’s claim processing system.

BACKGROUND

The administrative simplification provisions of HIPAA mandated the implementation of those standardized transaction and code sets adopted thus far by DHHS by October 16, 2002. Concerns about the healthcare community’s readiness to implement the adopted standards by the October deadline led Congress to pass the ASCA, which gave covered entities an extension under certain circumstances. The covered entity must submit a document requesting the extension and outlining how it plans to meet the new deadline of October 16, 2003. The covered entity must also begin testing the new system beginning April 2003.

THE COMPLIANCE PLAN

ASCA required CMS to create a model plan that could be used to satisfy the compliance document requirements. The model is divided into four sections: 1) information about the covered entity and contact information; 2) the reason for filing the extension request; 3) an implementation budget; and 4) an implementation strategy. This last section has three phases: 1) HIPAA awareness; 2) operations assistance; and 3) development and testing.

Covered entities are not required to use this format. A covered entity may create its own document as long as it contains the requisite elements. The form can be transmitted electronically or by hard copy. Electronic submissions will receive an electronic confirmation; hard copy submissions will not receive any confirmation of receipt. CMS recommends that the sender rely on the postal service for a confirmation of delivery if submitting by hard copy.

The model compliance form and CMS’s explanation about the ASCA requirements are available from the CMS web site. Go to:


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Mark Your Calendar for these Talks on Health Care & Employee Benefits Topics

4/25/02
What: “HIPAA Medical Records Privacy Regulations”
Where: Western Pension Benefits Seminar, Denver, Colorado
Who: Mike Kavanagh

5/10/02
What: “Recent Fraud & Abuse Settlements In and Around Colorado”
Where: Colorado Health & Hospital Association Meeting, Breckenridge, Colorado
Who: Robbi-Lynn Watnik

5/21/02
What: “Practical HIPAA.” (a half-day seminar)
Where: Cheyenne, Wyoming (place to be announced at a later date)
Who: Greg Piché, Brad Cave, and Robbi-Lynn Watnik

5/23/02
What: “Stark Compliance” and “Yes, Stark II Does Apply to Your Practice”
Where: Montana Medical Group Management Association Annual Meeting, Red Lodge, Montana
Who: Jill Keller and Greg Piché

5/31/02
What: “HIPAA Implementation and Compliance”
Where: EideBailly Healthcare Symposium, Billings, Montana
Who: Jill Keller

6/3/02
What: “HIPAA Operationalized”
Where: Health Care Compliance Association, Region VIII Compliance Conference, Rapid City, South Dakota
Who: Jill Keller and Robbi-Lynn Watnik
Long Term Care Notes

CMS PROPOSES SINGLE-TASK NURSING ASSISTANTS

Recognizing the shortage of certified nurse aides, CMS issued a proposed rule to give states the flexibility to let nursing homes hire individuals for the sole purpose of assisting certain residents during meals. A paid “feeding assistant” would be required to complete a state-approved training course meeting minimum subject requirements, such as: 1) feeding techniques; 2) safety and emergency procedures including the Heimlich maneuver; and 3) resident rights. Feeding assistants could only assist residents who do not have a clinical condition, as identified in the resident’s comprehensive assessment, requiring a higher level of assistance by more experienced nursing staff. CMS will accept comments on the proposal, published in the March 29, 2002, Federal Register (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=02-7344-filed), through May 28, 2002.

CO NURSING HOMES TO BE PART OF CMS PILOT PROJECT

Colorado is one of the six states participating in a Nursing Home Quality Initiative pilot program launched by CMS in mid-March. The other states are Florida, Maryland, Ohio, Rhode Island, and Washington State. A letter to all nursing home administrators in each of the six states from CMS Administrator Tom Scully states that the goal of the study is to “provide consumers with comparative information about nursing home quality measures” to assist them in selecting a nursing home that best meets their needs or the needs of a “loved one.” The study will also “provide Medicare and Medicaid certified nursing homes with information.” For additional information, go to: http://cms.hhs.gov/providers/nursinghomes/nhi/.

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