

Client *Urgent* Briefing

Urgent Legal News • March, 2001

HIPAA: PRIVACY REGULATIONS

DHSS now accepting additional comments

by Mary Z. Cornely

Background

In August, 1996, the United States Congress passed the Health Insurance Portability and Accountability Act ("HIPAA"). Although best known for promoting the portability of health insurance between employer group health plans, HIPAA includes a section entitled "Administrative Simplification," which addresses the need to enact a set of interlocking federal rules to establish standards and protections for patient healthcare information. Because Congress did not meet its August 21, 1999 deadline for the development of the privacy portion of these rules, responsibility for drafting these "privacy regulations" was transferred to the United States Department of Health and Human Services ("DHHS").

As most of you are aware, during the final days of the Clinton Administration, the DHHS did publish a comprehensive set of regulations governing the use and disclosure of most of the patient information that is created, recorded, and maintained by healthcare entities. While these privacy regulations were initially thought to be "final" as published in the Federal Register on December 28, 2000, the failure to timely submit them to Congress for review has caused two procedural setbacks. First, the effective date was postponed from February to April, 2001. Second, the Bush Administration was able to open the regulations to a new thirty-day public comment period.

*Public comments will be accepted until
5:00 p.m. on March 30, 2001
and may be submitted by mail, hand-delivery, or
through the Administrative Simplification website.*

This is welcome news to the healthcare industry which has been lobbying the Bush Administration to revise the requirements due to the anticipated procedural and financial burdens on the industry. It also gives Tommy Thompson, the new secretary of the DHHS, the opportunity to determine whether changes in the "final" privacy regulations are needed based on comments received by the DHHS over the next month. However, unless Congress decides to withdraw the HIPAA privacy regulations, they will become effective, in one form or another, on April 14, 2001.

A PRIMER ON THE REGULATIONS IN THEIR CURRENT FORM

Impact of the Privacy Regulations as Published

As currently published, the privacy regulations are more than 100 pages long and are accompanied by more than 1,400 pages of commentary. The impact of these extensive requirements is expected to be significant for every healthcare provider, healthcare plan, and

health data clearinghouse governed by the regulations ("Covered Entities"). In fact, not only must the Covered Entities comply with the new rules, but any person or organization that performs functions (such as claims processing, billing, accounting and consulting services) on behalf of a Covered Entity involving the use or disclosure of certain healthcare information ("Business Associates") must comply as well. All healthcare information that can be used to identify an individual patient, whether it be written, electronically transmitted, or verbally communicated, is protected by the regulations.

Documentation and Personnel Requirements

The published regulations, with few exceptions, require Covered Entities to obtain "consents" and "authorizations" prior to using or disclosing protected healthcare information, even for uses and disclosures related to treatment, payment, and healthcare operations. This will require a host of new internal policies and procedures for each Covered Entity in order to ensure that every disclosure includes only the minimum amount of healthcare information necessary.

Covered Entities are also required to designate a "privacy officer" to develop and implement privacy policies, educate employees of the Covered Entity on the privacy requirements, policies and procedures, penalize employees who do not comply with the policies, and process patient complaints.

New Federal Patient Rights

In addition, the published regulations grant patients significant new legal rights with regard to accessing their own medical records. While most states currently limit access to healthcare information or restrict it altogether, the current federal regulations provide patients the right to review, copy, and correct errors in their personal medical records. Not only will patients be afforded access, they must also be notified in writing about how their protected information is being used, maintained and disclosed. Patients may also request an accounting of the disclosures of their protected healthcare information over the previous six years. Further, patients may amend their health records, or may insert a statement of disagreement if the Covered Entity believes the information to be accurate and complete. A patient's right of access does not extend to certain types of healthcare information, however, and access may be denied under certain circumstances.

Enforcement and Potential Liability

The DHHS has broad powers to inspect health records in order to determine the extent of a Covered Entity's compliance with the HIPAA requirements. Sanctions range from \$100 per infraction for unintentional violations, to \$250,000 and ten years in prison for will-

ful violations with the intent of using the information for commercial advantage, personal gain or malicious harm. Covered Entities face additional exposure because they are also required to monitor the actions of their Business Associates. For sanctioning purposes, the actions of Business Associates are attributable to the Covered Entity if the Covered Entity was aware of the violation and failed to take the proscribed action.

While the privacy regulations don't create a provision under which a patient may sue for violation of the federal law, state law may still permit actions against Covered Entities for violations of patient privacy. For instance, in Ohio the state Supreme Court has recognized that individuals may bring suit for "the unauthorized, unprivileged disclosure to a third party of nonpublic medical information that a physician or hospital has learned within a physician-patient relationship." This means that, even though the HIPAA regulations don't provide patients the authority to sue for a violation of their privacy rights, a violation of the privacy regulations (e.g., "an unauthorized disclosure to a third party of nonpublic medical information") may well supply the basis for a civil suit under Ohio common law.

The Impact on State Law

As if compliance with these sweeping new regulations isn't burdensome enough, Covered Entities must also be mindful of state laws which regulate the use of healthcare information. While most states don't have comprehensive health privacy laws comparable to the new federal regulations, many states do have detailed, stringent standards for certain kinds of information, such as mental health, genetic testing, and HIV/AIDS records. Where state laws provide greater protection for the privacy of healthcare information or allow the patient greater access to his/her own information, Covered Entities must comply with both the new federal requirements and existing state law. If, however, a Covered Entity's compliance with a state privacy provision will cause it to violate the federal regulations, then the federal regulations control and preempt the state provision. Therefore, Covered Entities must evaluate their privacy policies for compliance with the


new federal regulations and with more stringent state statutory and common law requirements.

The Importance of Aggressive Planning

The current effective date for the published privacy regulations is April 14, 2001, with full compliance required by April 14, 2003 for most Covered Entities. Healthcare providers, plans and data clearinghouses will have two years to familiarize themselves with the new mandates; assess their current compliance efforts; develop an appropriate compliance program; draft the required forms, policies and procedures; implement the program; and prepare to monitor their compliance. It is currently unclear what effect the additional comment period will have on the federal privacy requirements, and, ultimately, on the healthcare industry. There's little doubt, however, that the healthcare industry should prepare for significant changes in its handling of patient information.

How W&H Can Help

Each Covered Entity will be required to carefully analyze and apply the final privacy regulations to their current business functions, structure, and information handling practices. New job descriptions, policies, procedures and forms will also have to be developed and ready for utilization before the mandatory compliance date. Walter & Haverfield's Health Care attorneys are familiar with the federal requirements, are closely monitoring the progression of these regulations, and are reviewing the government's responses to concerns expressed by the healthcare industry. We are available to answer questions you might have regarding the submission of comments to the DHHS on a particular point of concern, and to assist you in bringing your healthcare entity into compliance with the privacy regulations.

If you would like further information regarding the current published regulations, or would like to learn more about providing comments for consideration, please contact Mary Cornely or Kevin O'Connor at 216-781-1212. 

NEED FURTHER INFORMATION?

For more information on this or other health care related issues, please contact one of the following Health Care attorneys:

Mary Z. Cornely	mcornely@walterhav.com
Robert J. Crump	rcrump@walterhav.com
Michael J. Jordan	mjordan@walterhav.com
Mark P. McGrievy	mmcgrievy@walterhav.com
Kevin M. O'Connor	koconnor@walterhav.com
Charles R. Schaefer	cschaefer@walterhav.com
Marleina T. Thomas	mthomas@walterhav.com
Amy L. Woodhall	awoodhall@walterhav.com

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Walter & Haverfield LLP

Attorneys at Law / Foreign Legal Consultants / International Law Agents
1300 Terminal Tower Cleveland, Ohio 44113-2253 216/781-1212 Fax 216/575-0911
www.walterhav.com