

# Staying Ahead

with Saul Ewing

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## Life Sciences Law

### HIPAA Complaint Process Established as Security Rule Compliance Date Approaches

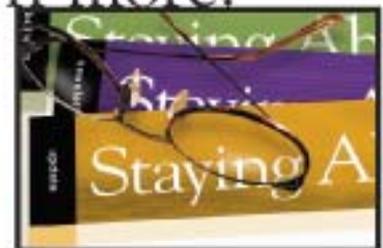
#### What happened?

The U.S. Department of Health and Human Services (HHS) published a notice describing the procedures for filing complaints for alleged violations of the various HIPAA rules, including the Security Rule, several weeks before the Security Rule's April 20, 2005 effective date.

#### What does it mean?

Within a week following the effective date of the Security Rule, there will be a complaint process in place for persons who believe a covered entity is not complying the Security Rule.

Learn more.



Turn the page to read more.

## The Complaint Process

On March 25, 2005, HHS published a notice (70 FR 15329 et seq.) (the "Notice") setting forth the procedures to file a complaint with the Centers for Medicare and Medicaid Services (CMS) of alleged non-compliance by a covered entity with regard to the following HIPAA rules: the Security Rule; the Transaction and Code Set Rule; the National Employer Identifier Rule; the National Provider Identifier Rule; and, the National Plan Identifier Rule which has not yet been finalized.

Importantly, this Notice does not apply to the HIPAA Privacy Rule. Alleged complaints with regard to compliance with the Privacy Rule are handled by the HHS Office of Civil Rights.

The Notice provides that complaints must meet the following requirements:

- Be filed on paper or electronically; faxed complaints will not be accepted;
- Describe the acts or omissions that constitute the alleged violation;
- Provide all relevant contact information for the complainant and the covered entity; and
- Be filed within 180 days of when the complainant knew or should have known that the act or omission occurred, unless waived by CMS.

CMS will acknowledge its receipt of the complaint with 14 days of receipt. After the complaint has been reviewed by CMS (no timeframe for such review is provided in the Notice), CMS may notify the complainant that the complaint has been accepted for processing and further review; ask the complainant to provide additional information; close a complaint if it does not state a claim. A complaint may be withdrawn at any time, though CMS may choose to continue its investigation of the covered entity.

The Notice provides that CMS will work with covered entities to obtain voluntary compliance. If CMS accepts a corrective action plan from a covered entity, the Notice states that CMS will actively monitor the plan and the covered entity will be required to periodically report to CMS its progress towards compliance.

If CMS finds that a violation exists, the Notice provides that HHS will pursue other options including, but not limited to, civil money penalties.

Unlike the Office of Civil Rights, CMS has significant experi-

ence in dealing with provider compliance issues. Accordingly, covered entities should be on notice that CMS may be prepared to respond quickly and directly to complaints against covered entities.

The Notice and its complaint process is effective April 25, 2005, five days after the required compliance date for the HIPAA Security Rule.

## The HIPAA Security Rule

If you are a covered entity, you are expected to be well on your way to ensuring compliance with the Security Rule. If you have not yet begun the risk assessment and analysis process, there is still time to ensure compliance by April 20, 2005, but that window is rapidly disappearing.

The Security Rule sets forth comprehensive administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information.

The Security Rule includes a series of standards and implementation specifications – the latter of which are either required or addressable by the covered entity. As its name suggests, a "required" specification must be achieved by the covered entity. For the "addressable" implementation specifications, the covered entity must decide whether the specification is a reasonable and appropriate security measure, or unreasonable and/or inappropriate. The Security Rule stresses the importance of good documentation of the decision-making process.

The greatest advantage, and difficulty, of the Security Rule is its flexibility. There is not a one-size-fits-all approach. A covered entity must take into account many factors in developing its compliance plan.

Achieving compliance with the Security Rule by April 20, 2005 is not the end of the covered entity's responsibility. It is merely the beginning. As security threats emerge and change, the covered entity must have systems and personnel in place to respond accordingly. The complaint process in the Notice will help ensure broad accountability by covered entities.

*This W•H•I•M<sup>SM</sup> was prepared by Bruce D. Armon, a partner in Saul Ewing's Business Department. For more information, please contact Bruce at (215) 972-7985 or barmon@saul.com.*

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