



American Hospital
Association

Legal Advisory

AHA's Legal Advisory, a service to members, is produced whenever there is a significant development that affects the job you do in your community. If you do not receive all eight pages of this advisory, visit "What's New" at www.aha.org.

Understanding the Proposed HIPAA Enforcement Process

A Message to AHA Members:

The U.S. Department of Health and Human Services (HHS) published proposed enforcement regulations (enforcement rule) for the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) in the April 18 *Federal Register*. The proposal extends rules for investigating and enforcing the HIPAA medical privacy standards to the remaining HIPAA administrative simplification regulations, including security, transactions standards, code sets and identifiers. HHS' goal in extending the applicability of the rules is to create a single enforcement policy for all the HIPAA administrative simplification provisions.

The AHA's April 27 *Hospital Highlights* outlined key provisions of the proposed rule and identified areas of concern that we expect to address in our comment letter to HHS. *Hospital Highlights* and a copy of the proposed enforcement rule are available on our HIPAA Web site at www.aha.org. This *Legal Advisory*, developed with our outside HIPAA counsel Hogan & Hartson, will help hospitals and health systems understand how the proposed HIPAA enforcement process generally is expected to operate.

In the proposed rule, HHS reaffirms its current commitment to using a complaint-based approach to HIPAA enforcement, initiating investigations or enforcement proceedings only upon receiving a complaint of possible violations brought by another party. HHS indicated that this approach could change in the future, however, and that the department could introduce compliance reviews to aid in enforcement. The AHA is concerned that HHS provides no additional detail regarding such compliance reviews.

In the proposed enforcement rule, HHS divides the enforcement process into three parts:

- Investigation of possible violations, including securing the cooperation of the target of the investigation to remedy any violations.
- Calculation and imposition of civil money penalties (CMPs).
- Pre-hearing and hearing phases of enforcement.

Generally, the proposed rule is guided by existing rules established by the Office of Inspector General for administering CMPs pursuant to section 1128A of the Social Security Act relating

to the submission of false and/or fraudulent claims. As a result, the enforcement rule makes use of many of the institutional resources already in place at HHS, such as the administrative law judges (ALJ) and appeals to an HHS review board, for HIPAA enforcement.

To ensure that your organization is prepared to respond quickly and effectively should any investigatory and other enforcement proceeding be initiated, check off the following items from your to-do list:

- ✓ Share this *Legal Advisory* with your legal counsel, compliance officer and privacy officer.
- ✓ Evaluate the effectiveness of your organization's efforts to address and respond to complaints about potential HIPAA violations that you receive directly from third parties.
- ✓ Consider in advance of initiation of any investigation or other enforcement proceeding, how your organization will respond to and work cooperatively with HHS enforcement agencies to investigate and resolve complaints of potential HIPAA violations.
- ✓ Develop and implement organizational processes and procedures for responding quickly to a *notice of proposed determination* from HHS that penalties for any HIPAA violations are warranted.
- ✓ Consider submitting comments to HHS on the proposed enforcement rule. Our comment letter will be posted soon at www.aha.org. HHS is accepting comments until June 17.

For more information about AHA efforts on HIPAA implementation and enforcement, contact the AHA at (800) 424-4301, or visit http://www.hospitalconnect.com/aha/key_issues/hipaa/index.html. The AHA remains committed to providing member hospitals with the latest resources and tools on HIPAA.

Sincerely,

Melinda Reid Hatton
Vice President & Chief Washington Counsel

June 8, 2005



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The U.S. Department of Health and Human Services (HHS) published proposed enforcement regulations (enforcement rule) for the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) in the April 18 *Federal Register*. The proposal extends the rules for investigating and enforcing the HIPAA medical privacy standards to the remaining HIPAA administrative simplification regulations, including security, transactions standards, code sets and identifiers. By extending the applicability of the rules, HHS creates a single enforcement policy for all the HIPAA administrative simplification provisions.

The AHA's April 27 *Hospital Highlights* outlined key provisions of the proposed rule and identified areas of concern. Some of the significant changes introduced by the proposed rule are:

- Violations for which a civil money penalty (CMP) is imposed, including the identity of the violator, will be made public.
- HHS can impose penalties of \$100 per violation, up to a maximum of \$25,000 per year for "identical violations" of any of the administrative simplification rules
- An "identical violation" is defined narrowly, and a single act may create multiple violations. As a result, the actual maximum penalty may be much higher than \$25,000.
- If multiple entities are responsible for violations, the Administrative Law Judge (ALJ) can impose the maximum penalties on each entity.
- Entities that operate as affiliated single covered entities are jointly and severally liable for penalties.
- An entity is responsible for any violation committed by its "workforce," which includes volunteers and certain independent contractors.
- HHS may use statistical sampling as evidence of the number of violations or to establish other factors used to calculate the amount of penalty.
- The appeals process adds an administrative appeal before appeal to the United States District Court.

Hospital Highlights and a copy of the enforcement rule are available on the AHA's HIPAA Web site at www.aha.org. The AHA's comment letter to HHS will be posted soon.

This AHA *Legal Advisory* will help hospitals understand how the proposed HIPAA enforcement process generally is expected to operate. Understanding the enforcement process and how it might potentially impact hospital operations in advance of any enforcement action will be critical to avoiding adverse actions and lengthy and resource intensive proceedings.

General Background and Definitions

The proposed rule divides the enforcement process into three parts:

- Investigation of possible violations, including securing the cooperation of the target of the investigation to remedy any violations (45 CFR 160 subpart C).
- Calculation and imposition of civil money penalties (45 CFR 160 subpart D).
- Pre-hearing and hearing phases of enforcement (45 CFR 160 subpart E).

Generally, the rule is guided by the rules established by the Office of Inspector General for administering CMPs pursuant to section 1128A of the Social Security Act relating to the submission of false and/or fraudulent claims. As a result, the proposed enforcement rule makes use of many of the institutional resources already in place at HHS, such as the administrative law judges (ALJ) and appeals to an HHS review board.

Currently, HHS uses a complaint-based approach to HIPAA enforcement, initiating investigations or enforcement proceedings only upon receiving a complaint of possible violations brought by another party. However, HHS indicated that this approach could change in the future, and that it could introduce compliance reviews. No additional detail regarding such compliance reviews has been provided.

HHS reaffirmed its desire to achieve voluntary compliance, and expressed a preference for continuing to work with covered entities cooperatively to implement changes necessary to achieve compliance without imposing penalties. To this end, the Secretary retains the discretion to settle cases at many different stages without issuing enforcement notices or formally instituting proceedings. But when an entity negotiates and undertakes a corrective action plan to resolve any noncompliance, HHS does **not** consider the noncompliance resolved until the entity performs the full corrective action plan.

Penalties may be imposed for violating any of the “administrative simplification provisions” of HIPAA. The administrative simplification provisions include any requirements of the privacy and security rules and the regulations on transactions and code sets. Thus, if a requirement is violated – regardless of whether a requirement is a standard, an implementation specification, or any other categorization of a HIPAA requirement – the Secretary can impose penalties. A “violation” is defined as any failure to comply with an administrative simplification provision.

The definition of “person” has been expanded to encompass all legal entities, including state and federal programs or entities, to ensure that all entities considered “covered entities” under HIPAA are subject to the enforcement rule.

Compliance and Investigations

Complaint. Anyone who believes an entity has violated a HIPAA requirement may file a complaint within 180 days of discovering the alleged violation. The complaint must describe the acts or omissions that the complainant believes violate HIPAA. Although not required to, HHS then may conduct an investigation into the allegations. HHS also may conduct compliance reviews, even if it has not received a specific complaint.

Investigation. When HHS conducts an investigation, covered entities are required to keep whatever documentation HHS specifies for determining compliance, cooperate with investigations conducted by HHS, and permit access to information necessary for the investigation. HHS may issue investigational subpoenas, enforceable in U.S. District Court, to secure the production of evidence and the testimony of witnesses.

Testimony will be taken under oath. Attendance of any non-witnesses is at the discretion of HHS, but a witness is entitled to have an attorney present. The witness may or may not be provided a copy of the transcript at the discretion of HHS, but in all cases the witness will have the opportunity to review the transcript and recommend clarifications. Any evidence may be used by HHS in any of its activities, and may be offered into evidence in any judicial or administrative proceeding. Retaliation against a witness for testifying in an investigation, filing a complaint, or opposing any act that is unlawful under HIPAA is prohibited.

Resolution. After the investigation, if HHS determines that the covered entity has violated any HIPAA provisions, HHS will attempt first to resolve the matter by informal means. Typically, this will take the form of entering into an agreement to take corrective action. If such steps resolve the violation, HHS will inform the covered entity in writing. If the matter is not resolved by informal means, HHS will inform the covered entity and the covered entity then has 30 days to provide written evidence of any mitigating factors or affirmative defenses, which are specified in the regulations. If HHS reviews the written evidence and determines that penalties are warranted, HHS will then inform the entity through a notice of proposed determination.

Notice of Proposed Determination. The notice of proposed determination must describe the facts regarding the alleged violations, state why the violations subject the entity to penalties, the factors considered in determining the proposed penalty, and instructions for responding to the notice. If HHS is relying on statistical sampling (see “Statistical Sampling” below) to calculate the number of violations and penalty amount, the notice of proposed determination must describe the study relied upon and briefly describe the sampling technique used.

Penalties

Under the proposed rule, HHS will impose penalties if it determines that a covered entity has violated any HIPAA administrative simplification requirements. Although HHS retains discretion in seeking voluntary compliance and settling matters, once it determines that there are violations, the penalty must be imposed unless the entity establishes an affirmative defense.

Liability. The possible liability for violating HIPAA requirements extends beyond officers or employees of a particular entity. If there is a violation by multiple entities, penalties will be imposed against each entity. In addition, all entities that are part of an affiliated single covered entity (ASCE) are jointly and severally liable for violations by that ASCE. Liability extends to entities according to federal common law of agency; an entity is liable for the actions of all of its “workforce” members which would include non-employees such as hospital volunteers and certain independent contractors working on-site at the hospital.

Amount of Penalty. HHS may impose a penalty of up to \$100 for each violation, which may not exceed \$25,000 for “identical” violations in any one calendar year. When determining the amount of penalty, HHS will examine:

- the nature of the violation – what is the purpose of the violated rule?
- the circumstances – what were the consequences?

- the culpability of the entity – was it intentional? Was it beyond the entity’s direct control?
- history of prior offenses;
- financial condition of the entity, and
- “such other matters as justice may require.”

Also important in calculating the penalty is determining what constitutes identical violations, what constitutes a single violation, and how to count the number of violations.

Identical Violations. Identical violations are violations of a single HIPAA requirement. Determining whether violations are identical depends upon the provisions of the statute or regulation and not upon other factors such as whether the acts involve a single patient’s information, constitute part of the same transaction, or are with a single trading partner. If a requirement of one provision of a HIPAA regulation is repeated in more general form in another provision of the same regulation, then penalties may be imposed only for one of the two provisions. Violating different requirements within the same rule are not identical violations. A single act that violates multiple HIPAA regulations can count as multiple violations.

Number of Violations. HHS retains significant discretion to determine which variables to consider when counting the number of violations, so long as HHS remains consistent from case-to-case. The variables HHS can consider are: the number of permissible actions (or inactions); the number of persons involved in the violation (which may be patients, employees or other persons affected); or the amount of time during which the violation occurred. When the amount of time is at issue, generally each day would be considered a single violation, and a single type of violation occurring over multiple days would yield penalties of \$100 per day.

Affirmative Defenses. Affirmative defenses first must be presented in response to notification from HHS that informal resolution has failed. There are three affirmative defenses that are an absolute defense to imposition of CMPs:

- The entity could establish that the violation is also punishable under the criminal provisions of HIPAA. As the preamble to the proposed rule notes, this defense is unlikely to be invoked because it requires the entity to admit that it has committed a criminal offense.
- The entity could establish that it did not know of the violation, and through the exercise of reasonable diligence could not have known of the violation. Knowledge requires not only that an entity know of the acts that constitute the violation, but also that the entity has the specific knowledge that a particular act was actually a violation of the HIPAA regulations. If only a lower level employee did have, or should have had, knowledge of the violation, the default is to impute the knowledge to the entity, unless the entity can establish an affirmative case for why it should not be imputed.
- The entity can escape liability if it can show that the failure was due to a reasonable cause – and not willful neglect – and the entity cures the violation within 30 days from when the entity discovers (or should have discovered) the violation. Reasonable cause would be circumstances that are outside of the entity’s direct control. (Willful neglect is analogous to acting recklessly – *i.e.*, an entity knows there is a risk of a problem and does not take any steps to alleviate it.)

Hearings

An entity is entitled to a hearing before an ALJ when HHS proposes to impose penalties.

Requesting Hearing. The entity has 60 days from the time it receives a notice of proposed determination to make a written request for a hearing before an ALJ. If the entity fails to request the hearing within that time, HHS will impose the penalty. In the request for a hearing, the entity must admit, deny or explain each of the facts that HHS outlined in its notice of proposed determination. In addition, the entity must outline any affirmative defenses or other legal and factual grounds for opposing the penalty.

Discovery. Parties to hearings may make document requests on any other party. However, requests for admission, written interrogatories, depositions and all other forms of discovery are not permitted.

Exchange of Exhibits and Witness Statements. Not more than 60 days, nor less than 15 days, before the scheduled hearing, the parties must exchange witness lists, copies of the proposed witness's prior written statements, and copies of proposed exhibits. If one party tries to admit evidence that was not exchanged as required, the ALJ must exclude that evidence unless extraordinary circumstances existed. If extraordinary circumstances existed, the evidence may be admitted unless it would substantially prejudice the other party, in which case it may be excluded or the hearing may be postponed to allow time for a proper rebuttal. The regulations do not define the term "extraordinary circumstances."

Prehearing Conferences. At least one prehearing conference must be scheduled. These conferences can be used to simplify the issues, reach agreement on stipulations of fact or authenticity of documents, explore the possibility of submitting the case on a stipulated record, waive an oral hearing, limit the number of witnesses, schedule dates, arrange for discovery of documents, and other procedural matters.

Rights of Parties. Each party is entitled to be represented by an attorney, participate in any conferences, present evidence, present and cross-examine witnesses, present oral arguments and submit written briefs.

Hearing. Before imposing penalties, the ALJ must conduct a public hearing. HHS has the burden of going forward and the burden of persuasion with all issues of liability and any aggravating factors. The burden of proof is by the preponderance of the evidence – in other words, is it more likely than not that the facts alleged by HHS are true. The covered entity has the burden of going forward and the burden of persuasion regarding any affirmative defense, any challenge to the amount of the proposed penalty, and any claim that the penalty should be reduced or waived because it is excessive relative to the violation.

Witnesses generally must give live testimony at the hearing. Written statements may be substituted, however, if the opposing party is presented with the written statements when the witness lists are exchanged and has had the opportunity to subpoena the witness for cross-examination at the hearing.

Evidence. The ALJ makes determinations on whether to admit evidence. The Federal Rules of Evidence do not govern the admission of evidence, but the ALJ may apply them where appropriate. Evidence must be excluded if it is irrelevant or immaterial, if its probative value is outweighed by the danger of unfair prejudice, or if it is privileged under federal law.

Statistical Sampling. HHS may use statistical sampling as evidence of the number of violations or to establish other factors used to calculate the amount of penalty. If such sampling is based

upon an appropriate sample, and computed with valid statistical methods, it is *prima facie proof* of the number of violations and the existence of factors relevant to establishing the penalty amount. In other words, if the entity fails to rebut the statistical evidence or demonstrate that the statistical sampling methodology is flawed, the ALJ may use the sampling study as a basis on which to impose penalties.

A brief description of the sampling technique must be included in the notice of proposed determination, but the entity may not receive a copy of the actual statistical sampling study until 15 days before the hearing. As a result, the entity has a short period of time to review, investigate, critique, and/or rebut the statistical study used to establish the number of violations.

Appeal. Any party may appeal to a panel of three members of the HHS Departmental Appeals Board. The notice of appeal must be filed within 30 days of service of the ALJ decision. The notice of appeal must be accompanied by a written brief specifying exceptions to the ALJ decision. Any party then has 30 days to file opposition briefs. The appeals board may permit reply briefs. The appeals board may not consider issues that could have been – but were not – raised with the ALJ. On disputed issues of fact, the standard of review is whether the ALJ decision was supported by “substantial evidence” in the record as a whole. On disputed issues of law, the standard is whether the decision is erroneous.

Harmless Error. At every stage of the proceedings, the ALJ and appeals board are instructed to disregard any error in the admission of evidence that does not affect the substantial rights of the parties.