American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

June 14, 2005

Mr. Alex M. Azar II
General Counsel
US Department of Health and Human Services
Office of General Counsel
Attention: HIPAA Enforcement Rule
330 Independence Avenue, SW
Washington, DC 20201

RE: RIN: 0991–AB29 – HIPAA Administrative Simplification; Enforcement; Proposed Rule, (70 *Federal Register* 20224) April 18, 2005.

Dear Mr. Azar:

On behalf of our nearly 4,800 member hospitals, health care systems, and other providers of care, the American Hospital Association (AHA) appreciates this opportunity to comment on the U.S. Department of Health and Human Services (HHS) proposed enforcement regulations (enforcement rule) for the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The AHA supports HHS' goal of creating a single enforcement policy for all the HIPAA administrative simplification provisions by extending the applicability of 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.

Compliance and Guidance. The enforcement rule addresses the procedural processes for imposing civil money penalties (CMPs) for a violation, including substantive detail about the basis of liability and the determination of CMP amounts. In the rule, HHS also reiterates its commitment "to promoting and encouraging voluntary compliance with the HIPAA rules through education, cooperation, and technical assistance." The AHA endorses this continued emphasis on voluntary compliance.

The AHA urges the Office of Civil Rights (OCR) and the Centers for Medicare & Medicaid Services (CMS) to fulfill the enforcement rule's promise to "continue to work on educational and technical assistance materials, including additional guidance on compliance and enforcement and targeted technical assistance materials focused on particular segments of the health care industry." Generally, hospitals need *more specific, operational level* guidance that would provide greater clarification of the HIPAA requirements and identify appropriately scalable best practices for compliance. The AHA refers HHS to our previous

recommendations for continuing guidance on the medical privacy rule implementation contained in the AHA's comments on the interim final enforcement regulation. The AHA especially urges OCR to issue guidance and other assistance, consistent with previous recommendations, to decrease the burdens of the accounting of disclosures and the business associate requirements of the medical privacy rule. In addition, hospitals need additional information to help educate their business associates about the business associates' use and/or disclosure of protected health information (PHI) in a manner that is consistent with the hospital's HIPAA obligations and specified in the contractual provisions of the business associate agreement.

HHS also indicates in section 160.308 of the enforcement rule, that while compliance and enforcement activities currently are largely complaint based, HHS "may also . . . conduct[ ] compliance reviews to determine if a covered entity is in compliance." However, HHS provides no additional information about these compliance reviews. The AHA urges HHS to provide covered entities with information about when and how a compliance review would be initiated and conducted and the manner and timing in which covered entities would be informed about such reviews.

CMPs and Liability. The AHA is pleased that HHS is proposing limited improvements to certain enforcement rule provisions related to calculating and notifying a covered entity of CMPs. The AHA, for example, is pleased that in section 160.408, the enforcement regulations propose that OCR and CMS will consider mitigating factors in determining the appropriate amount of a CMP, and we recommend that HHS maintain this provision in the final enforcement regulations. Additionally, consistent with the AHA's recommendations on the interim final enforcement regulations, HHS proposes to amend the requirements in section 160.420 concerning the notice of proposed determination to provide covered entities with information regarding the circumstances OCR or CMS considered when determining the amount of the proposed penalty. The AHA also recommends that HHS retain this requirement in the final regulation to ensure that hospitals have more information regarding any penalty proposed.

The AHA, however, is concerned that the methodologies for establishing violations and the amount of any penalty do not provide covered entities with sufficient information to predict and limit their liability and may result in the imposition of CMPs that may significantly exceed the statutorily permitted maximum penalty. Specific recommendations for modifying these methodologies are provided in the attached detailed comments.

Likewise, the provisions imposing liability on a covered entity for the violations incurred by individuals and organizations over whom the covered entity may be able to exercise little real control inappropriately expands the potential liability exposure of all covered entities. The AHA is pleased that, in response to its previous comments and consistent with the HIPAA medical privacy rule, the proposed enforcement regulations clarify that covered entities are not liable for the actions of their business associates, including clearinghouses, so long as the covered entities take certain action required by the privacy rule. The AHA urges HHS to maintain this position in the final enforcement regulations. HHS, however, should revise the remaining liability provisions as recommended in the AHA's attached detailed comments.

Rights to Defend and Appeal. The AHA also is very concerned that the proposed enforcement rule significantly restricts and limits a covered entity's ability to present a defense and appeal an adverse ruling, including the imposition of a CMP. Many provisions of the rule are unfairly weighted in the government's favor to the serious detriment of covered entities. Specifically, the AHA's attached detailed comments address the following, any number of which, taken together, are in their present form a significant impediment to mounting a defense or appeal: (1) the severely restricted ability of covered entities to rebut the statistical sampling report; (2) the "extraordinary circumstances" standard for failure to timely exchange exhibits and witness statements; (3) the inability to depose prior to the hearing or question at the hearing the government's statistical sampling expert; (4) the ability of the administrative law judge (ALJ) to admit prior evidence of witnesses which were not subject to cross examination by the covered entity; (5) the requirements regarding hearing requests; (6) the limited nature of discovery and the lack of obligation to share exculpatory evidence; (7) the ALJ's discretion about applying the Federal Rules of Evidence; (8) the very broad harmless error rule which significantly restricts a covered entity's appeal rights; and (9) the limited authority of the ALJ and correspondingly broad discretion provided to the Secretary.

HHS should not prevent covered entities from putting on a proper defense and having meaningful appeal. The AHA urges HHS to reconsider some or all of these detailed proposals to ensure that covered entities receive a fair hearing, are able to present a meaningful defense, and have a fair opportunity to appeal an adverse ruling.

Publicity of Penalties Imposed. The AHA is troubled by HHS' intention to publicize the identity of CMP recipients and, in particular, HHS' expectation that consumers will use the information to choose a health care provider. In section 160.426, the proposed enforcement rule takes the approach of making available to the public information about the imposition of a CMP, including the identity of the violator. HHS' rationale for publicizing violators is that "knowledge of the imposition of a civil money penalty for violation of the privacy rule could be important to health care consumers, as well as to covered entities throughout the industry."

In comments to the 2003 interim final enforcement regulations, the AHA had asked that HHS make available to covered entities information about violations, proposed solutions and good practices in a form that does *not* identify the violator. Making information available in an unidentified format would allow covered entities to understand how OCR and CMS interpret and apply the HIPAA regulations in specific cases and would encourage remediation of problems and violations discovered through the enforcement process. The information would enable covered entities to gain a better sense of the types of compliance problems that are occurring and the misunderstandings that exist regarding the application of the HIPAA regulations.

The notion that information about a violation of the technical requirements of HIPAA is useful or relevant to consumers' health care decision making is flawed. Consumers should not make their health care decisions based on HIPAA's technicalities—these are irrelevant to the quality of care patients receive from a provider.

As the number of complaints filed with OCR for incidents that are not HIPAA violations suggests, many consumers do not understand these complicated rules. Moreover, although

health care consumers who are informed that a hospital violated the HIPAA medical privacy rule are likely to believe the hospital does not adequately protect patient privacy, most violations of the medical privacy rule are *not* the result of an impermissible use or disclosure of patient information and likely to be only technical in nature. The AHA appreciates that compliance with technical requirements of the administrative simplification provisions, including the technical requirements of the HIPAA medical privacy rule, is important, and that accrediting entities need to know of these facts. The potential for seriously misleading the public about the meaning of the medical privacy rule violations where no impermissible use or disclosure occurred is an unwarranted and irresponsible policy. Moreover, publicizing violations of the HIPAA transactions and code sets rule will confuse the public because focusing on these behind-the-scenes administrative activities could lead consumers to make poor health care decisions based on irrelevant information.

In addition as we discuss in our detailed comments, the methodologies used to establish violations and penalties, including statistical sampling and the number of days a requirement was not met, are not easy to understand. As a result, a published violation could assert that during a three-month period Hospital A had 1,110 violations of the medical privacy rule—which may refer to nothing more than that the entity was unable to document during this period that receipt of the Notice of Privacy Practices was acknowledged by persons admitted to the emergency room, or that HHS has determined that processes used to collect data for the accounting of disclosures with respect to 1,110 patients do not have all of the details needed to comply with its guidance. As a result, the statement Hospital A paid several thousand dollars in fines due to 1,110 violations of the Privacy Rule arguably is misleading and could panic individuals into distrusting their provider.

Publication of a HIPAA violation also could unfairly impact hospitals' business and reputation. For example, a hospital may be identified as a HIPAA privacy rule violator when it has a rogue employee who acted inappropriately and against hospital policy. Publication of the violation could affect the hospital's reputation and business even though the employee's actions are not accepted hospital practice and the violation was a rare occurrence. In addition, if one hospital is held liable for the violations of another hospital in its affiliated single covered entity, as HHS proposes, consumers or other entities would be making decisions based on faulty and inaccurate information—believing one hospital violated HIPAA when technically another hospital was responsible for the violation.

Finally, publication of violators also is worrisome because it is not entirely clear when a penalty is considered final for these purposes. Publishing the imposition of a penalty before all of a hospital's appeals are exhausted, including appeals to federal courts, is premature when the penalty could be reversed on appeal.

The AHA urges HHS to rethink its proposal to make public the violator. As a policy matter, entities (and potentially, the public) would benefit from knowing the types of penalties imposed and the kinds of violations that OCR and CMS are finding and, thus, the AHA encourages the publication of this information <u>without the identity of the violator</u>. The negative and unintended effects of publicizing the identity of the person or entity on whom a CMP was imposed far outweighs any alleged benefit.

Thank you for the opportunity to submit these and the attached detailed comments containing recommendations for enhancing the enforcement rule. The AHA looks forward to working with HHS to make sure that the HIPAA enforcement process appropriately encourages improvements in hospitals' compliance programs. If you have any questions about the AHA's comments, please contact Lawrence Hughes, regulatory counsel and director, member relations at (202) 626-2346.

Sincerely,

Melinda Reid Hatton
Vice President and Chief Washington Counsel

Attachment

American Hospital Association
Detailed Comments on HIPAA Administrative Simplification; Enforcement; Proposed Rule
70 *Federal Register* 20224, April 18, 2005

COMPLIANCE AND INVESTIGATIONS

Informal Processes [§ 160.304]
In the enforcement regulations, HHS reiterates the intention of the Office of Civil Rights (OCR) and the Center for Medicare & Medicaid Services (CMS) to resolve any compliance issues through informal means. HHS also states, however, that HIPAA "*require[s]* the Secretary to impose a civil money penalty on any covered entity which the Secretary determines has violated an administrative simplification provision, unless the covered entity establishes an affirmative defense." (Emphasis added.) It is unclear how an informal resolution of violations is possible given HHS' position that when a violation is found, a civil monetary penalty (CMP) *must* be imposed. The AHA is concerned that such a position may jeopardize OCR's and CMS' ability to resolve violations informally.

It is critical that OCR and CMS keep their promise to resolve HIPAA issues informally. The implementation of the HIPAA regulations has been difficult, complicated and confusing and much of the confusion, particularly with regard to the HIPAA privacy and security rules, have not been addressed in guidance from OCR. Thus, it would be unfair and unreasonable to impose strict penalties on hospitals where a violation is discovered without first attempting to resolve the issue informally. In many cases, a hospital will have acted in good faith in implementing the regulations and will simply have misunderstood or misinterpreted the requirement at issue. In other cases, a mistake or error may have caused the HIPAA violation. It would be excessive to impose a CMP on a hospital for these and similar misinterpretations or mistakes.

Certainly, hospitals should be required to remedy a HIPAA violation, for example, by changing a practice that HHS believes is inconsistent with the regulations, but the good faith mistakes and errors described above are precisely the types of situations that would benefit from voluntary compliance and informal resolution. Moreover, the matter can be addressed much more rapidly through informal means than if a CMP is imposed. The CMP hearing and appeal process is more costly in terms of time and money for OCR and CMS than if the issue was resolved informally. All parties, including patients, benefit from the prompt and informal resolution of violations, whenever possible. Thus, the AHA encourages OCR and CMS to keep its promise to covered entities to resolve issues informally as a matter of course.

Investigational Subpoenas [§ 160.314]
The proposed enforcement regulations permit the Secretary to issue subpoenas to require the attendance and testimony of witnesses and the production of any other evidence. To the extent investigational subpoenas seek the production of documents, there should be language that protects documents covered by the attorney-client and attorney work product privileges and regarding the protection of confidential documents. The AHA encourages HHS to add these protections to the section on subpoenas in the final enforcement regulations.

In addition, subpoenas should be confined to seeking testimony and documents related to the HIPAA provisions being enforced. OCR and/or CMS should not be able to use an alleged

violation of one HIPAA requirement to request discovery on unrelated matters. The AHA respectfully requests that HHS provide such a limitation in the final enforcement regulations.

The subpoena provision also does not appear to permit covered entities to challenge subpoenas. The AHA recommends that a provision allowing covered entities to challenge a subpoena issued by OCR and/or CMS be added to the final enforcement regulations. If the Secretary can enforce subpoenas in the U.S. District Court, then covered entities should be able to challenge subpoenas in such court as well. This is only fair and equitable and ensures due process to covered entities.

The section on subpoenas also proposes, for good cause, to limit witnesses to the inspection of the official transcript of their testimony rather than permit the witnesses to obtain a copy of the transcript. It is unclear what might constitute "good cause" for limiting witnesses to inspecting the official transcript of their testimony. The AHA urges HHS to define the term or, at least, provide some examples.

CALCULATION AND NOTIFICATION OF CMPs

Identical Requirement [§ 160.404]
The HIPAA statute limits the total amount of a CMP imposed "for all violations of an identical requirement or prohibition during a calendar year." The enforcement regulations propose to interpret an "identical violation" quite narrowly, considering a single violation to have occurred when "a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart." This means that a single act often will create multiple violations. For example, many violations of the HIPAA security regulations also could automatically be considered a violation of the HIPAA privacy regulations because the privacy rule requires covered entities to implement safeguards to prevent improper uses and disclosures of protected health information (PHI).

The AHA is concerned that this narrow interpretation of an identical violation could result in significantly more liability than is appropriate or than covered entities could reasonably expect. Moreover, this interpretation renders almost meaningless the CMP cap set forth in the HIPAA statute for a violation, suggesting this narrow interpretation was not intended. The AHA requests that HHS develop a more concrete, broad and reasonable interpretation of identical violation so that covered entities can predict and limit their liability, as intended by the HIPAA statute.

Number of Violations [§ 160.406]
The proposed enforcement regulations provide the Secretary with full discretion to determine, on a case-by-case basis, how many violations a covered entity has made. HHS proposes to use the following variables for calculating the number of violations: (1) the number of times the covered entity failed to engage in required conduct or engaged in a prohibited act; (2) the number of persons involved in, or affected by, the violation; and (3) the duration of the violation, counted in days. The enforcement regulations state that the Secretary could use more than one variable at a time—multiplying, for example, the number of days times the number of people affected. This discretion is of great concern, particularly because it is not reviewable by an administrative law judge (ALJ). Although each violation is capped at a maximum penalty of $25,000, the definition of what constitutes the same violation and the variables available to determine the number of violations together create the potential for

significantly greater covered entity liability. A violation that may, on its face, seem small could quickly hit the maximum penalty given the Secretary's ability to use multiple variables in assessing the penalty. This calculation method for number of violations is discretionary, indefinite and does not allow covered entities to assess their possible liabilities.

The AHA is concerned about the unchecked discretion provided to the Secretary in assessing CMPs. Hospitals will be unable to predict with any reasonable accuracy their likely exposure. HHS states that it "welcome[s] comments on this approach, the options that were considered, and other potential options for determining the number of violations." The AHA urges HHS to utilize a more definite and fair method of calculation. HHS, for example, could establish one particular calculation method for each HIPAA rule or specify the types of violations for which HHS would use each method. HHS should provide more concrete guidance on the calculation of CMPs. In addition, at the very least, HHS should not allow the Secretary to use multiple variables to assess a CMP at the same time, in the same case. Thus, in any given case OCR and CMS should be required to choose one variable for purposes of setting the CMP amount.

Statistical Sampling [§ 160.563]
The enforcement regulations permit HHS to use statistical sampling as evidence of the number of violations. This method is inherently inaccurate and is likely to lead to prejudicial results. Further, because the regulations allow statistical sampling, but in section 160.516 prohibit the taking of depositions, there is no way to subject the "expert" on statistical sampling to adverse examination until the hearing, if even then (as discussed below). In addition, although section 160.420(a)(2) requires the Secretary, in the notice of proposed determination, to describe the statistical sampling study relied upon by the Secretary and briefly to describe the sampling technique used by the Secretary, it is unclear what constitutes a "brief" description. A brief description is most likely insufficient to provide the covered entity with enough information to challenge adequately the technique. Finally, because the covered entity may not receive a copy of the actual statistical sampling study until 15 days before the hearing, it has a very short period of time in which to review, investigate, critique and/or rebut the statistical study used to establish the number of violations. Accordingly, the AHA requests that HHS reconsider its proposal regarding statistical sampling to eliminate its use for imposition of a CMP or, alternatively, to permit depositions of statistical sampling experts and require HHS to give covered entities more detail of the technique utilized in sufficient time to allow entities to provide a meaningful defense and rebuttal.

Affirmative Defenses [§ 160.410]
Under subsection (b)(1), a covered entity must raise the defense that its action constitutes a criminal offense and therefore cannot also be subject to civil money penalties. A covered entity should not be required to incriminate itself; instead, a covered entity should be permitted to wait to raise this affirmative defense until after the U.S. Department of Justice, if it decides to do so, initiates criminal proceedings. Thus, the AHA urges HHS to allow this affirmative defense to be raised at such later time.

Such a change is necessary to comport with the plain language of the statute. As a recent Memorandum of the U.S. Department of Justice Office of Legal Counsel dated June 1, 2005 stated: "the Secretary may not impose civil sanctions for the commission of an act that subjects a person to the possibility of criminal prosecution, regardless of whether the person is in fact punished criminally." As this statement indicates, the statute appears to flatly prohibit the Secretary from imposing a CMP on conduct that also could be subject to criminal

penalties--whether the covered entity is prosecuted under the criminal statute is irrelevant. Accordingly, this limitation in the HIPAA statute is an absolute bar, rather than an affirmative defense, and should be treated as such.

LIABILITY FOR OTHERS [§ 160.402]

Affiliated Single Covered Entities
Under the proposed enforcement regulations, hospitals that participate in an affiliated single covered entity (ASCE) with other hospitals under common ownership or control will be held jointly and severally liable for the violations of other hospitals within the ASCE. This is true even where a covered entity can prove that another entity in the ASCE is actually responsible for the violation. Specifically, HHS states that "no covered entity in an affiliated covered entity could avoid a civil money penalty by demonstrating that it was not responsible for the act or omission constituting the violation or that another covered entity member of the affiliated covered entity was the culpable entity." This provision could impose significant potential CMP liability on a single hospital for a violation by another or multiple other hospitals. Moreover, if violations are made public, as proposed, one hospital could be identified as receiving a penalty, but the penalty would actually be for a violation by another hospital.

The AHA is concerned about the potential liability exposure hospitals would face under this proposal and the potential effect on hospital business if the public were not aware that one hospital received a penalty for another hospital's violation. Although it may be understandable for HHS to hold as jointly and severally liable the entities participating in an ASCE to ensure that someone is accountable for a violation, it leads to unfair consequences if an entity is prohibited from establishing that another entity participating in the ASCE is actually responsible for a particular violation. Placing the responsibility on the entity that committed the violation may be important for corporate structure and finance purposes and especially with regard to the publication of the violator. The ASCE structure is one of the "fictions" created by the agency to make it feasible to implement the complex requirements of the privacy rule in modern health care environments. It is unwarranted to substitute this regulatory fiction for the corporate form and structure that establish the basis for enterprise liability under the laws of the United States. Thus, the AHA urges HHS to allow covered entities participating in an ASCE to provide evidence that another entity is actually responsible for the violation and require HHS, in such circumstances, to proceed against the truly responsible entity.

Organized Health Care Arrangements
Participating in an organized health care arrangement (OHCA) does not make the hospital liable for the violations of other members of the OHCA. However, the proposed enforcement regulations state, "it may be a factor considered in the analysis." It is unclear what HHS intends by this statement. The AHA is concerned HHS may use a hospital's participation in an OHCA with another person or entity that violates HIPAA to impose liability on the hospital. For example, suppose a physician agrees to a patient's request for restrictions on use of a patient's information by the hospital, but fails to take the necessary steps under the hospital's HIPAA procedures for ensuring that the request is implemented. The enforcement regulations make the hospital's interests adverse to those of the physician; the hospital will have to defend itself aggressively from the imposition of penalties in order to avoid an unjust result. Most hospitals participate in an OHCA with other entities or individuals (*e.g.*,

physicians with privileges at the hospital) and, historically, have often faced significant challenges in ensuring that medical staff comply with the hospital's procedures. Clarification of this statement is essential to ensure that participation in an OHCA does not increase hospitals' potential liability exposure.

Agents
The enforcement regulations propose that covered entities be held liable for "the actions of any agent, including an employee or other workforce member, acting within the scope of the agency or employment." This would include independent contractors and volunteers working onsite whom the hospital has designated as part of its workforce for purposes of HIPAA compliance. HHS "specifically request[s] comment on whether there are categories of workforce members whom it would be inappropriate to treat as agents."

The AHA recommends that HHS exclude volunteers and independent contractors from the definition of agents for purposes of assessing and imposing CMPs. These relationships are not typically agency relationships. Although hospitals may have some control over such individuals when working onsite at the hospital, the hospital's control is not akin to that of an employee or the agent of the hospital. As a result, the hospital should not face liability for violations by volunteers and independent contractors, so long as the hospital has provided the requisite instruction as to their obligations under the privacy rule.

RIGHTS TO APPEAL AND DEFEND

Witnesses and Depositions [§§ 160.516; 160.518]
The enforcement regulations propose to require the parties to exchange witness lists, copies of witness' prior statements and copies of exhibits not more than 60 days or less than 15 days before the hearing. This time period is potentially problematic, in particular, given HHS' ability to use statistical sampling evidence. Because HHS allows the use of statistical sampling in determining the number of violations and HHS is permitted to introduce statistical sampling at the hearing to establish its *prima facie* case against a covered entity, it is critical that covered entities have a fair opportunity to rebut such evidence. Although the government must provide a brief description of its statistical sampling technique in the notice of proposed determination, this "brief description" is likely insufficient for a covered entity to mount an appropriate and full defense against such methodology or the assumptions made in conducting such sampling.

Thus, the first time that a covered entity would have access to expert reports or statements regarding the statistical sampling used to establish the proposed CMP is 15 days before the hearing. This is insufficient time for the covered entity to obtain its own expert and/or conduct its own review of the methodology and calculation to rebut the sampling. In addition, because the covered entity is required to provide the government with its witness statements and exhibits at the same time, the covered entity will be barred from adding its own expert to testify at the hearing or adding expert statements or exhibits for purposes of rebutting the government's statistician report. Section 160.518(b)(2) requires the ALJ to exclude witnesses and exhibits not timely exchanged unless the ALJ finds "extraordinary circumstances" existed. It is unclear what would constitute extraordinary circumstances. Given the need for covered entities to rebut statistical experts whose information they will not receive until the exchange of witnesses and exhibits, however, this standard seems unnecessarily high. "Good cause" would be a much more reasonable and fair standard.

Moreover, because depositions are not permitted, covered entities lose another potential opportunity to question the government's statistician in an effort to understand and defend against the conclusions and assumptions made in establishing the proposed CMP. A covered entity cannot subject the expert to adverse examination until the hearing, if at all. This is extremely prejudicial to the covered entity.

Finally, it is unclear whether the government's statistician is even required to testify. It appears that the government may be able to rely solely on the expert's prior testimony in other cases and/or the expert's report. The proposed regulations permit the admission of "prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony." Because depositions are not allowed, this must mean that testimony from experts in *other* cases may be used. This is prejudicial because the covered entity has not had an opportunity to subject the testimony to adverse examination and the facts of different cases are likely not identical. Therefore, the expert testimony in one case may not be appropriate for use in a different case.

As such, the AHA requests that HHS revise the enforcement regulations to:

- permit depositions, at least with regard to expert witnesses, including the government's statistical expert;
- allow covered entities a fair opportunity to rebut such experts by permitting the addition of rebuttal witnesses and exhibits after the 15 day period and/or requiring the government to provide more detailed information to the covered entity regarding its statistical sampling calculations, methodology and assumptions sufficiently before the 15 day deadline;
- require the admission of witnesses and exhibits not timely exchanged to be judged on a "good cause" rather than extraordinary circumstances standard or, at least, define the term and provide examples;
- require, at the covered entity's request, the testimony at the hearing of the government's statistical sampling expert; and
- prohibit the use of prior sworn testimony of experts unless from the specific case at issue.

Request for a Hearing [§ 160.422]

The interim final enforcement regulations required hospitals to file a request for a hearing within 60 days of receiving a notice of proposed determination. In the hearing request, a hospital must include an admission, denial or explanation of the findings of fact contained in the notice and any defenses the hospital has and the hospital's legal and factual basis for opposing the penalty. The AHA's comments to these regulations made clear that in order to ensure hospitals appropriate due process and time to investigate and develop their defenses and explanations, HHS must either extend the time limit for requesting a hearing or permit less specificity in the request. The AHA is disappointed that HHS has adopted the same standard in the proposed enforcement regulations. HHS responded to the AHA's comments on this issue by noting that, in HHS' view, the hospitals will be aware of HHS' investigation and details of the alleged violation long before receiving a notice of proposed determination and, thus, should have sufficient time to conduct an internal investigation and develop appropriate defenses. There is no process or requirement that would support HHS' statement, so the AHA is concerned that hospitals will not have the information necessary to provide their defenses and explanations, particularly if statistical sampling is used, until the notice of proposed determination is received—at the earliest. As noted in our prior comments, this requirement also does not mirror the Office of the Inspector General procedural regulations

for CMPs. Thus, the AHA urges HHS to reconsider the requirement that covered entities include defenses, explanations and all opposition in the hearing request.

Moreover, the enforcement regulations do not provide any information regarding what rights covered entities have with regard to receiving information about the complaint. It is critically important to covered entities' investigation, compliance efforts and defense that they are provided with a copy of the complaint. After a penalty is proposed, the covered entity is given a "description of the findings of fact regarding the violations with respect to which the penalty is proposed." The AHA urges HHS to require explicitly that OCR and CMS provide covered entities with a copy of any complaints filed for which the covered entity is being investigated and for which a CMP may be imposed. Without such information, covered entities' internal investigations, efforts to remedy any violation, and any attempt at a defense or explanation will be hindered. HHS should not be concerned about retaliation against the complainant, as such is prohibited by HIPAA, but if necessary, HHS can provide the complaint with the complainant's identity redacted.

In addition, the ALJ is *required* to deny a hearing request if the covered entity fails to raise an issue that may properly be addressed at the hearing. This requirement seems particularly restrictive given the short time period within which a covered entity can investigate an alleged violation and develop defenses to be raised at the hearing. Thus, the AHA respectfully requests that HHS permit, *but not require*, the ALJ to deny the hearing request under § 164.504(d)(1)-(3) and eliminate § 164.504(d)(4) to ensure covered entities are provided a fair opportunity to request a hearing and develop an appropriate defense to be raised at the hearing.

Finally, under the proposed enforcement regulations, if a covered entity fails to request a hearing within 60 days after receipt of the notice of proposed determination, the penalty will be imposed. The AHA is concerned that this automatic imposition of a penalty does not allow for the possibility that a covered entity may have good cause for its failure to request a hearing within the allotted time. For example, the notice could have been sent to the wrong address or a person who left the company, or a low-level employee received the notice but did not promptly forward it within the company. Accordingly, if a covered entity can show good cause for failing to request a hearing within the 60-day time period, the covered entity should be entitled to a hearing.

Discovery [§ 160.516]
The proposed enforcement regulations do not appear to include a requirement that OCR and/or CMS hand over potentially exculpatory information to the entity being investigated. The AHA recommends that this obligation be added to the final enforcement regulation to ensure that covered entities are able properly and fully to defend themselves. The obligation to provide exculpatory evidence should include handing over exculpatory interview reports or statements obtained by the government of persons who will not be called as witnesses by that party. In addition, HHS should allow requests for admissions, depositions (see previous discussion), and written interrogatories in the discovery process. This will ensure that covered entities are able to mount a proper defense. Moreover, these processes promote judicial economy, making the hearing more efficient.

Evidence [§ 160.540]
Subsection (b) provides the ALJ with the option of applying the Federal Rules of Evidence. This optional use of the Federal Rules of Evidence is insufficient and does not allow entities

to know what evidence will be admissible at the hearing or what rules of evidence will apply. The Federal Rules of Evidence should apply to provide more certainty to the parties. At a minimum, the use of hearsay should be prohibited (except pursuant to the hearsay exceptions of the Federal Rules of Evidence). The AHA urges HHS to require in the final enforcement regulations that ALJs apply all of the Federal Rules of Evidence. If HHS is unwilling to require application of all the rules, HHS should at least require the ALJ to abide by the rules on hearsay.

Harmless Error [§ 160.522]
This provision is far too broad, particularly given the extremely limited discovery available to covered entities under the enforcement regulations. The harmless error section severely limits and restricts a covered entity's ability to appeal an adverse ruling and/or the imposition of a CMP. The AHA urges HHS to use a less broad and restrictive harmless error rule.

ALJ Authority [§ 160.508]
The enforcement regulations address the authority of an ALJ in connection with the imposition of CMPs. The AHA is very concerned that the ALJ does not have sufficient authority to provide a hospital with much relief. The proposed limits on the ALJ's authority, in conjunction with the Secretary's unfettered discretion, cause significant concern.

The enforcement regulations propose to prohibit the ALJ from reviewing the Secretary's exercise of discretion regarding the choice of variables under § 160.406. This means that the Secretary's calculation of the number of violations is unreviewable, except by a U.S. District Court. Because the number of violations is a factor in determining the amount of the penalty, at least one major aspect of the amount of the penalty is unreviewable. The AHA urges HHS to permit the ALJ to review the Secretary's choice of variables in assessing the penalty amount to ensure fairness for covered entities.

Finally, under the interim final enforcement regulations, the ALJ may "affirm, increase or reduce the penalties imposed by the Secretary." The AHA was concerned and commented to HHS that this language suggested the ALJ may be unable to determine that no violation had occurred. In the proposed enforcement regulations, HHS clarifies and confirms that the ALJ may issue findings of fact and conclusions of law and, thus, may determine that no violation has occurred. The AHA is pleased that ALJs have the authority to evaluate whether there was a violation in the first place and urges HHS to retain this position in the final enforcement regulation.

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