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June 16, 2003

Thomas A. Scully  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-0010-IFC  
Post Office Box 8010  
Baltimore, MD 21244-8010

**RE:** CMS-0010-IFC - Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings; Interim Final Rule, (68 *Federal Register* 18895), April 17, 2003.

Dear Mr. Scully:

On behalf of our nearly 5,000 member hospitals, health care systems, networks and other providers of care, the American Hospital Association (AHA) appreciates this opportunity to comment on the interim final rule establishing certain procedural rules for the imposition of civil money penalties on entities that violate standards adopted under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Like the Department of Health and Human Services (HHS), the AHA believes that publishing this first installment of the HIPAA enforcement regulations (known as the enforcement rule) even though it is limited in scope will nevertheless assist hospitals in understanding HHS' approach to HIPAA enforcement.

The AHA fully supports HHS' continued commitment to working informally with hospitals and other covered entities to resolve compliance issues and help them improve their compliance with the HIPAA regulations. The AHA is encouraged that, rather than being punitive, the Office of Civil Rights (OCR) and the Centers for Medicare and Medicaid Services (CMS) initially intend to provide assistance and education to covered entities. Member hospitals report that a lot of misinformation about HIPAA continues to be presented, which is affecting compliance efforts. Thus, the AHA encourages OCR to continue its efforts to educate covered entities and the public and provide technical assistance to ensure accurate information about the HIPAA requirements is widely accessible to covered entities.

In the preamble to the enforcement rule, HHS specifically states that guidance efforts and other technical assistance regarding the HIPAA privacy rule will continue, "as OCR learns from its compliance activities and from those who are implementing the Privacy Rule where additional guidance and assistance are needed." 68 *Fed. Reg.* at 18897. The AHA is pleased that OCR is open to learning where problems with implementation have arisen and providing guidance or

assistance. To aid in this effort, we have attached detailed comments highlighting several key HIPAA privacy rule concerns where OCR could provide additional assistance and clarification that would be helpful to hospitals.

Additionally, the AHA generally is pleased with the procedural requirements set forth in the enforcement rule itself. The AHA endorses HHS' efforts to track, in most cases, the HHS Office of Inspector General (OIG) civil money penalties procedures, as Congress specifically required in enacting the HIPAA law. There are a few instances, however, where HHS departed from these OIG procedural requirements without any justification for such differences. In our detailed comments to this letter, the AHA discusses these differences, which we believe jeopardize the due process rights of hospitals and other covered entities. Our recommendation relating to each of these differences is that HHS *track more closely* the OIG procedures in the HIPAA enforcement rule.

Nevertheless, these procedures, even when modified as the AHA suggests, may be inappropriately cumbersome for enforcing the HIPAA rules for electronic transactions and code sets. The AHA supports HHS' intent to adopt an enforcement rule that establishes procedural requirements that would apply uniformly to the enforcement of all HIPAA administrative simplification regulations and provide for the use of the same procedures for a violation of the HIPAA privacy, security, and electronic transactions rules. The AHA believes, however, that enforcement of the transactions rule should place significantly more focus on informal and quick resolution of issues.

The processing and payment of health care claims is one of the key HIPAA transactions. If a hospital receives the Secretary's notice of proposed determination for a violation of the transactions rule, such notice could lead to a cessation of claims submission or could result in a significant delay in the submission of claims as the hospital reverts to paper processes in order to correct or avoid an alleged violation. The adverse impact of such enforcement process with respect to the transactions rule — loss of revenue to the hospital or significant disruptions in the claims processing and payment cycles — far outweighs the offense — use of an incorrect code or format. Moreover, delays in, or cessation of, claims filing and payment that impede the flow of money into hospitals could affect patient access to quality care. Thus, the AHA urges HHS to take a less punitive and more cooperative approach to enforcement of the transactions rule and avoid using these cumbersome processes, or provide a mechanism for uninterrupted electronic submission of claims for payment and receipt of payment, when a violation is found to ensure that the processing and payment of claims continues.

Moreover, HHS or CMS should make clear in a subsequent enforcement rule or other guidance how covered entities should handle a violation of the HIPAA regulations, particularly the HIPAA transactions rule, by the covered entity's clearinghouse. Although the clearinghouse is a covered entity under HIPAA, it is also a business associate of covered entities. Accordingly, if a hospital discovers that its clearinghouse has engaged in conduct that violates HIPAA, hospitals

are concerned that, if they are unable to terminate their agreement with the clearinghouse and, therefore, must report the violation to CMS, the hospital itself may be held liable for a violation of HIPAA since the clearinghouse was acting on the hospital's behalf. Moreover, if the hospital must continue to use the clearinghouse for the submission of claims for payment, it is unclear whether this is a subsequent and continued violation of HIPAA. HHS should reassure covered entities that they will not be held responsible for a violation of HIPAA by their clearinghouses so long as the covered entity terminates the relationship with the clearinghouse or, if termination is not feasible, reports the violation to HHS. HHS also should make clear that, when termination of the relationship with the clearinghouse is infeasible, continued use of the clearinghouse after the violation is reported to HHS does not constitute a violation for the hospital. Otherwise, hospitals could be unable to receive payment for their services, stopping the flow of money to hospitals and jeopardizing patient care and essential operations.

In the preamble to the enforcement rule, HHS states that it subsequently will publish the substantive portions of the enforcement rule and will provide for notice and comment on such provisions. The AHA appreciates the opportunity to comment on these additional provisions because input from hospitals and other covered entities in the development of the HIPAA regulations will help HHS to appropriately improve compliance efforts. The AHA is concerned, however, that while HHS states that it "intend[s] to revise the procedural rule by the expiration date," 68 *Fed. Reg.* at 18895, HHS does not indicate whether it will provide for further comment on the revised procedural rule in light of its relation to the substantive provisions of the enforcement rule. The substantive provisions are essential to covered entities' understanding of how HHS intends to enforce the HIPAA regulations and whether the procedures outlined in this first part of the enforcement rule are appropriate in light of such enforcement activities. The AHA, therefore, respectfully requests that, in addition to comments on the substantive aspects of the rule, HHS provide a subsequent opportunity for notice and comment on the revised procedural provisions after the substantive provisions of the enforcement rule are promulgated.

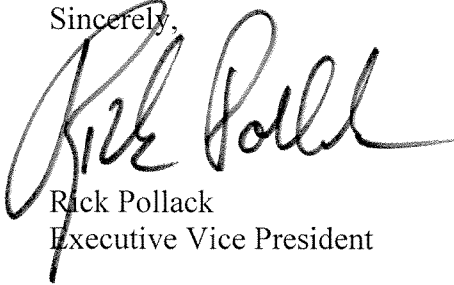
In addition, the AHA suggests that OCR and CMS share with hospitals and covered entities any findings of violations, proposed solutions and good practices in a form that does not identify the violator. This information will allow covered entities to understand how OCR and CMS interpret and apply the HIPAA regulations in certain cases and will encourage remediation of problems and violations that are discovered through the enforcement process. Covered entities will gain a better sense of the types of problems entities are encountering and the misunderstandings that exist regarding the application of the HIPAA regulations.

Thank you for the opportunity to submit these and the attached detailed comments containing recommendations for improving the procedural portion of the HIPAA enforcement rule and identifying privacy issues of continuing concern.

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We look forward to working with you to make sure that the efforts related to HIPAA enforcement appropriately encourage improvements in hospitals' compliance programs. If you have any questions about these remarks or our detailed comments, please contact Melinda Hatton, vice president and chief Washington counsel at (202) 626-2336 or Lawrence Hughes, regulatory counsel and director, member relations at (312) 422-3328.

Sincerely,

A handwritten signature in black ink, appearing to read "Rick Pollack". The signature is fluid and cursive, with the first name "Rick" and last name "Pollack" clearly distinguishable.

Rick Pollack  
Executive Vice President

Attachment

**American Hospital Association**

**Detailed Comments on the Civil Money Penalties: Procedures for Investigations,  
Imposition of Penalties, and Hearings; Interim Final Rule  
68 Federal Register 18895, April 17, 2003**

- **Continuing Needs for Guidance on Privacy Rule Implementation**

Hospitals report that they are looking for further guidance and technical assistance from HHS to correct the misinformation about HIPAA that persists and to help them improve their compliance with specific requirements of the HIPAA medical privacy rule. Generally, hospitals indicate that they would like to see HHS provide *more specific, operational level* information that would provide greater clarification of the rule's requirements and identify appropriately scalable best practices for compliance with these requirements. HHS should address immediately the key concerns discussed below in order for the guidance to be of most benefit to hospitals.

**Decreasing the Burden of Accounting of Disclosures**

The AHA urges OCR to issue additional guidance and assistance regarding the accounting of disclosures requirement in the privacy rule. As numerous hospitals and other covered entities have indicated, this requirement is a significant impediment and administrative and financial burden for mass disclosures of information made for certain licensing and public health purposes. The AHA recommends that OCR find and provide information on workable alternative solutions to the accounting of disclosures requirement.

More specifically, the AHA urges OCR to provide guidance that recognizes alternatives to providing individualized accountings in these cases. For example, OCR should clarify that disclosures required for a covered entity to maintain its license and continue to function as a health care provider or plan are health care operations disclosures and, therefore, not subject to the accounting of disclosures requirement. OCR also should permit covered entities, for certain mass reporting of public health and health oversight data where identifiable patient information is disclosed, to provide individuals with a generalized list of these types of disclosures, to whom they are made, for what purpose, and the general time-frame within which they are made. This alternative to the individualized accounting would save hospitals from the needless administrative task of confirming that a particular patient's information was included in a disclosure and on what date an individual's information actually was disclosed. Thus, a hospital that discloses information on cancer patients to a state cancer registry would inform patients, via the general disclosures list, that such disclosures are made, but will not be required to set up a system to determine whether the patient had cancer or know the exact date on which the patient's information was disclosed to the registry.

**Clarifying Business Associate Relationships**

Another privacy rule issue that creates continuing concern and confusion for hospitals is who qualifies as a business associate and when are business associate agreements necessary. Many covered entities have been requiring business associate agreements with third parties who do not fit the definition of a "business associate," for example, providers to whom they disclose protected health information for treatment, including pharmaceutical and device manufacturers;

researchers; and medical staff. Out of fear of violating the privacy rule, some covered entities are even requiring everyone to whom they disclose protected health information to sign a business associate agreement, placing unnecessary and often inappropriate restrictions and obligations on the recipients of the information. Business associates that also are covered entities are liable for violating a business associate agreement, and covered entities are liable for known violations by their business associates, if they fail to take certain action. Thus, because of the potential liability associated with violations of business associate agreements, and the significant administrative burden imposed by negotiating such contracts, OCR should provide clear guidance stating that a business associate agreement may not be used when the rule provides other compliance mechanisms.

### **Expanding Education and Outreach to Physicians**

Hospitals are receiving frequent requests from physicians to provide them with HIPAA assistance and training. Hospitals are concerned that, if medical staff physicians—who are not employed by hospitals but included in an organized health care arrangement (OHCA) with the hospitals—are not properly educated about and trained on HIPAA, the hospital will be responsible for violations committed by those physicians. The AHA requests that OCR provide more outreach to and education of physicians and that OCR clarify in subsequent enforcement rule installments or guidance whether, and to what extent, hospitals will be held liable for violations of HIPAA by their medical staff or other OHCA participants.

### **Helping Patients and Their Families to Understand the Privacy Rule's Requirements**

Better education of and outreach to the public by OCR also is necessary. Hospitals are seeing high levels of frustration and confusion by patients and their family members, particularly regarding the notice and other additional paperwork required by the HIPAA privacy rule and misunderstandings regarding the effect of opting-out of the hospital directory. Hospitals, of course, are trying to inform patients and their families and friends about the privacy rule's requirements. Hospitals also continue to work with patients, family members, and friends to ensure that hospital policies and procedures specifically required to comply with the privacy rule do not frustrate their patients' desires to allow family members and friends to contact them and learn of their conditions. Hospitals could use additional assistance from OCR to help patients understand the obligations and limitations imposed on hospitals and how they will affect patients. OCR should seriously consider using an ongoing series of regional meetings that are open to the public as a means of increasing outreach and education to the public. In addition, OCR should provide hospitals with guidance about how best to balance their new obligations and limitations under the rule with their patients' desires and preferences for more extensive communication with family and friends.

### **Educating the Media about Limitations on Disclosure of Patient Information**

Media disclosures under the privacy rule are another area of confusion. The AHA respectfully requests that OCR issue a press release or other notice to the media detailing the restrictions the privacy rule places on hospitals' disclosures of information to the media. The media expect to be able to obtain certain patient information from hospitals and are increasingly frustrated by hospitals' unwillingness, without patient authorization, to provide information beyond that permitted by the privacy rule. The media need to be informed by OCR that, without patient

authorization, if the media do not inquire about the patient by name or if the patient has opted-out of the hospital directory, no information may be provided and, when information may be provided, the hospital only may release the patient's general condition. Although hospitals have attempted to explain the privacy rule requirements to the media, the media apparently believe that hospitals are using HIPAA as an excuse and that they are interpreting it too conservatively. It is important for hospitals to have good relationships with the media in their community and, thus, the AHA urges OCR to issue a guidance, press release or other statement specifying and confirming the limitations on media disclosures imposed by the privacy rule.

### **How Covered Entities Should Balance Their Provider and Employer Obligations under HIPAA**

Additional guidance also is needed with regard to the separation of covered functions and employer activities within a hospital. For example, if a nurse, physician or technician employed by the hospital receives care at the hospital and, during the rendering of such care, the hospital learns that the employee has a medical condition or drug addiction that could seriously compromise patient care, it is unclear whether the hospital may take action, in its employer capacity, to protect the safety of the hospital's patients. Hospitals are placed in untenable situations in these cases of choosing between protecting the privacy of the employee as a patient or the safety of the hospital's patients from employees' risky behavior or condition. The AHA believes a hospital's patient safety obligations supersede the individual employee's privacy rights in cases where patient care and safety are threatened, but urges OCR to clarify how hospitals are to handle these cases and help guide hospitals in making these critical choices. OCR also should assist covered entities in understanding their responsibilities with regard to other areas of conflict between HIPAA and federal, state or other legal obligations.

### **• Procedures for Investigations, Imposition of Penalties, and Hearings**

In the following sections, we recommend specific changes to the procedural requirements that are currently included in the HIPAA enforcement rule because they deviate significantly and inappropriately from the civil money penalties procedures of the HHS Office of Inspector General (OIG). While HHS indicates that these differences are necessary to expeditiously resolve compliance problems, the AHA believes that HHS' desire to adjudicate complaints quickly and impose penalties for compliance violations should not sacrifice the due process rights of hospitals and other covered entities. The AHA, therefore, urges that HHS *track more closely* the OIG procedures in the HIPAA enforcement rule.

### **Notice of Proposed Determination**

Under the enforcement rule, the Secretary is required to provide the covered entity with "written notice of the Secretary's intent to impose a penalty." 45 C.F.R. § 160.514. The rule requires that the notice include (1) the statutory basis; (2) a description of the findings of fact regarding the covered entity's acts or omissions; (3) the reasons why such acts or omissions are subject to a penalty; (4) the amount of the proposed penalty; and (5) the instructions for the covered entity to respond to the notice. These requirements are virtually identical to the HHS OIG civil money penalty procedures, *see* 42 C.F.R. § 1003.109, with one critical exception. The OIG procedures also require that the Secretary include in the notice of proposed determination "[a]ny

circumstances . . . that were considered when determining the amount of the proposed penalty.” 42 C.F.R. § 1003.109(a)(5).

The AHA urges HHS to include an identical requirement in the enforcement rule procedures for a notice of proposed determination. This additional requirement is particularly important in the enforcement rule in light of the requirement that covered entities include in their request for a hearing “the circumstances or arguments that the [covered entity] alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty.” 45 C.F.R. § 160.526(c). In order to respond appropriately in their request for a hearing, hospitals will need to know the circumstances the Secretary considered when determining the penalty. Moreover, because the administrative law judge (ALJ) may deny a hospital’s hearing request if it fails to raise an issue that may be addressed in a hearing and the denial is not subject to any right to appeal, it is essential that hospitals receive sufficient information in HHS’ notice of proposed determination to ensure that hospitals properly raise issues of dispute in their hearing request.

Perhaps this additional requirement was omitted because HHS has not yet promulgated the substantive requirements of the enforcement rule, which the department has stated will include determinations of violations and the calculation of penalties. The AHA nevertheless encourages HHS to require that the Secretary’s notice of proposed determination include information regarding the circumstances considered when assessing the amount of any penalty.

Moreover, it is equally important that HHS address the notice of proposed determination to the name of the hospital’s president and/or CEO. The hospital’s receipt of the Secretary’s notice – presumed to be five days after the date on the face of the notice unless a reasonable showing to the contrary is made – sets the enforcement process in motion. It marks the beginning of the very short time period the rule allows for a hospital to prepare and file a request for an ALJ hearing and, therefore, undeniably plays a key role in determining the course and outcome of the enforcement process. Every effort, therefore, must be made to ensure that the notice is directed to and received by the president and/or CEO of the hospital, the individual within the organization who has the knowledge and authority to act on the notice immediately. The AHA, of course, supports HHS’ use of certified mail to provide the notice and thereby call attention to its importance. We urge, however, that HHS take further steps to ensure that the notice receives immediate and proper attention from the hospital by explicitly addressing and directing the notice to the hospital’s president and/or CEO when HHS sends by certified mail the notice to the hospital. Information identifying the presidents and/or CEOs of all hospitals is widely available from a number of sources, including the AHA’s own annual publication entitled *AHA Guide® to the Health Care Field*.

### **Request for a Hearing**

After a covered entity receives the Secretary’s notice of proposed determination, the covered entity has 60 days to file a request for a hearing. The enforcement rule requires that a covered entity’s request for a hearing “clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the [covered entity] has any knowledge . . . [and] the circumstances or arguments that the [covered entity] alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty.” 45 C.F.R. § 160.526(c). This requirement significantly exceeds the OIG requirements for a



request for a hearing, which requires the inclusion of only “a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.” 42 C.F.R. § 1005.2(d). Because covered entities will have only 60 days from receipt of the Secretary’s notice to file their request for a hearing, the covered entity likely will not have sufficient time to investigate and develop its case, determine what occurred, and evaluate possible defenses to such allegations to provide the detail and specificity required by the enforcement rule.

In the preamble to the enforcement rule, HHS states that “the degree of specificity required generally parallels the requirements applicable to the notice of proposed determination.” 68 *Fed. Reg.* at 18899. The AHA believes it is inappropriate, however, to require the hospital’s hearing request to contain the same level of specificity required of the Secretary when giving notice of the Secretary’s intent to impose a penalty. While the Secretary will have had no time limitations on his investigation and development of allegations and case against the hospital, the hospital will have only 60 days from receiving such notice to ascertain relevant facts, develop fully its defense and prepare a response.

The AHA is concerned that requiring hospitals to provide their entire defense, admissions, explanations and arguments up front, before they have had sufficient time to develop their case and investigate what occurred, will result in inappropriate and unfair denial of hospitals’ due process rights. This is especially problematic given that the ALJ’s decision about whether to allow a hearing is based solely on the hearing request and the ALJ’s denial of a hospital’s request for a hearing is not subject to any appeal or review. HHS states that the purpose behind requiring additional information in the covered entity’s request for a hearing is to “promote procedural regularity and permit more timely and efficient resolution of the case between the parties or adjudication of the case by the ALJ.” *Id.* at 18899. The policies underlying the law, however, are not served by a speedy resolution that results in an incorrect determination. The inclusion of this additional information may result in more timely resolution of cases, but that speedy resolution comes largely at the expense of a hospital’s due process rights. If the hospital has not had sufficient time to investigate and properly set forth its defenses, the ALJ could easily decide that the hospital’s request fails to raise an issue that may be addressed in a hearing. The denial of the hospitals’ request for a hearing means that the Secretary’s proposed penalty will be imposed immediately, without the hospital having any right to appeal.

It is essential that covered entities receive due process prior to the imposition of penalties for a HIPAA violation, particularly in light of the potentially significant civil penalties that HHS may impose, as well as any follow up enforcement activity under state laws. The AHA, therefore, urges HHS to revise the requirements for a hearing request to track the OIG procedural requirements so that hospitals’ due process rights are protected and hospitals are not required to investigate and determine all possible challenges, disagreements and defenses in 60 days.

### **Party Exchange of Information**

Similar to the OIG procedures, the enforcement rule requires that the parties “exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits . . . at least 15 days before the hearing.” 45 C.F.R. § 160.540(a). Unlike the OIG

procedures, the enforcement rule allows the ALJ to order an earlier exchange of such information. Although the earlier exchange schedule will apply to HHS as well as the covered entity, the AHA is concerned that an earlier exchange of information could more adversely affect covered entities than HHS because hospitals, and other covered entities, likely will need as much time as possible to develop their case.

HHS could conceivably have up to six years to investigate an alleged violation and gather facts, exhibits and witnesses. In contrast, the first significant detail a hospital may receive about the violation could be in the notice of proposed determination from the Secretary, which immediately starts the 60-day clock running. The significantly shorter time that hospitals likely will have for preparation, investigation and development of their case means that allowing the ALJ the discretion to require the parties to exchange witnesses and exhibits more than 15 days before the hearing would be extremely prejudicial to hospitals and other covered entities. This is particularly troubling in light of the requirement that the ALJ exclude, absent a showing of extraordinary circumstances, any witness, exhibit or other evidence not exchanged with HHS within the time period set by the ALJ. *Id.* at § 160.540(b)(2). Accordingly, the AHA urges HHS to track the OIG procedures, removing the ALJ's discretion and requiring the exchange of witnesses and exhibits no earlier than 15 days prior to the hearing.

#### **ALJ Decision**

The AHA is pleased that HHS has permitted direct judicial appeal of the ALJ's decision, rather than requiring an additional administrative appeal. This will expedite resolution of the matter for covered entities, which is particularly important for alleged violations of the HIPAA transactions rule that, for example, pending resolution, could delay or halt a hospital's processing of claims and receipt of payment for health care services, threatening patient care.

The AHA, however, is concerned that under the enforcement rule, after the hearing, the ALJ must issue a decision that may *only* "affirm, increase, or reduce the penalties imposed by the Secretary." 45 C.F.R. § 160.564. The AHA is concerned that the rule does not appear to allow the ALJ to decide that no violation of HIPAA occurred or that no penalty should be imposed. HHS's finding of a violation, however, may be incorrect based on additional information provided by the covered entity during the hearing. The ALJ, therefore, should be permitted to render a decision that eliminates the penalty altogether or finds that no violation of HIPAA occurred. The AHA requests that HHS revise the enforcement rule procedures to provide explicitly for these findings by the ALJ.