

June 16, 2005

U. S. Department of Health and Human Services
Office of General Counsel
HIPAA Enforcement Rule
330 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0991-AB29

A representative number of North Carolina Healthcare Information and Communications Alliance, Inc (NCHICA) members have read the proposed rule at 45 CFR Parts 160 and 164 HIPAA Administrative Simplification; Enforcement, and we offer the following consolidated comments for your consideration.

III. General Approach

A. HHS's General Approach to Enforcement (page 20226)

The commentary states: "At present, our compliance activities are primarily complaint-based. Although our enforcement efforts are focused on investigating complaints, they may also include conducting compliance reviews to determine if a covered entity is in compliance."

Comment: Nowhere in the rule does it describe the process that will be used for compliance reviews. It does not address how possible compliance reviews would be coordinated between the Office of Civil Rights (OCR) and the Center for Medicare and Medicaid Services (CMS) if more than one component of the Administrative Simplification rule was involved in a potential violation. We suggest that you describe the process that will be used to coordinate the compliance reviews between OCR and CMS when there is a need for review for privacy, security and transactions rules within one system.

B. HHS's Approach to the Enforcement Rule (page 20227)

Comment: We believe the stated principles of the enforcement rule communicate a fair and reasonable philosophy. It is extremely important that this process be consistent, fair and flexible in its application.

IV. B. 2. b. "Violation" or "Violate" (page 20229)

"We propose to define a 'violation' (or 'to violate') to mean 'a failure to comply with an administrative simplification provision.'"

Comment: How does this fit with the addressable components in the security rule? This provision generated an exchange among NCHICA members. The concern seems to be that the potential variability in implementation among Covered Entities who may evaluate and act on their particular addressable risks might be held in non-compliance through administrative action and that the ruling would be made on subjective grounds. It would be helpful to articulate what the basis or standard for judging non-compliance for the addressable requirements will be.

B. 3. Section 160.312 -- Secretarial Action Regarding Complaints and Compliance Reviews (page 20230)

"The covered entity must submit any such evidence to the Secretary within 30 days of receipt of such notification."

Comment: 30 days is not a long enough period of time. We suggest that the time frame be extended to 60 days.

“Paragraph (b) of the current 160.312 provides that if the Secretary finds after an investigation or compliance review that no further action is warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant.”

Comment: Time frames should be added outlining deadlines for the Secretary to respond for final resolution of the investigation. We suggest that the Secretary respond within 60 days of completion of the investigation.

B. 4. Section 160.314 – Investigational Subpoenas and Inquiries (page 20230)

“Consistent with the practice under the OIG regulations, this provision would not permit the Secretary to propose substantive changes to the witness’s testimony.”

Comment: Does this imply that the Secretary has the discretion to determine whether a proposed transcript from a witness would be amended or not? This section is not clear in that it appears that the Secretary may choose to accept or not accept amendments to transcriptions despite requests from the witness. We suggest that only the witness has the ability to amend transcripts.

“Proposed 160.314(c) provides that, consistent with 160.310, testimony and other evidence obtained in an investigational inquiry may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.”

Comment: Evidence obtained in an investigational inquiry should only be used for disposition of investigational inquiry. The data collected as a part of the investigation should not be allowed to be used for any unrelated matters.

C. 1. Section 160.402 -- Basis for a Civil Money Penalty (page 20231)

“The use of the term ‘shall impose’ in section 1176(a) is more than a mere conveyance of authority to the Secretary to impose a penalty for a violation of an administrative simplification provision. If the Secretary finds in a notice of proposed determination that a covered entity has violated an administrative simplification provision, he is required to impose a penalty unless a basis for not imposing the penalty under section 1176 exists.”

Comment: We ask that the Secretary consider aligning this with the approach addressed later in the rule that allows the Secretary discretion in the imposition of fines. The two matters should be consistent in their application.

C. 1. b. ii. Agents (page 20232)

“We specifically request comment on whether there are categories of workforce members whom it would be inappropriate to treat as agents under 160.402c.”

Comment: Would the Secretary please re-evaluate students who are enrolled in an academic course of study supervised by school faculty for the purpose of enforcement. The control of these workforce members is somewhat different than the majority of workforce members. They are not our employees and are under the direct control of the academic institution; therefore, we have limited control.

C. 2. c. ii. Determining the Number of Violations (page 20235)

“Under this proposal, the policy for determining which variable(s) to use for which type of violation would be developed in the context of specific cases rather than established by regulation. Subsequent cases would be decided consistently with prior similar cases. This

option would defer more specific decisions regarding the appropriate variable(s) for counting penalties to such time as a case raising the HIPAA provision occurs.”

Comment: Who is responsible for this and how will it be accomplished? It is important to determine who will be accountable for managing the process of tracking and trending of violations, investigations and application of penalties. We believe that there needs to be assignment of tracking to a central entity and that the information be made available by general category of violation to covered entities via the CMS HIPAA website.

“After weighing the advantages and disadvantages of each approach, it was determined that it would be preferable to determine the appropriate variable(s) for particular types of violations based on the context of a specific case.”

Comment: It would be helpful to track and trend the violations and be specific in the application of enforcement. Consistency is critical. This information should be de-identified and accessible to covered entities for use with their HIPAA compliance programs.

“We propose to leave to the Secretary’s discretion the decision regarding when aggravating and mitigating factors will be taken into account in determining the amount of the civil money penalty.”

Comment: The section earlier on imposition of penalties should be aligned with the section on civil monetary penalties and should allow discretion of the Secretary in both instances.

C. 3. c. iii. Determination of the Cure Period (page 20239)

“The covered entity must also correct the violation during the 30-day period beginning when the person knew or should have known that the violation existed.”

Comment: We agree with the initial 30-day time frame to correct the violation but request an additional 30 days to fully resolve all issues identified.

C. 5. Section 160.414 -- Limitations (page 20239)

“We propose to move this section, which sets forth the 6-year limitation period provided for in section 1128A(c)(1), from subpart E to subpart D. We propose to do so because this provision applies generally to the imposition of civil money penalties and is not dependent on whether a hearing is requested. We also propose to change the language of this provision so that the date of the occurrence of the violation is the date from which the limitation is determined.”

Comment: We ask that the Secretary provide additional guidance on the application of record retention for HIPAA purposes. This section needs to be clarified further. Will a CE be in violation of the Administrative Simplification rules if it destroys records after the 6-year retention period that are then later requested as a part of an investigation? We suggest that the CE would not be considered in violation if they are in compliance with the 6-year retention period specified in the rule.

C. 11. Section 160.426 -- Notification of the Public and Other Agencies (page 20240)

“When a penalty proposed by the Secretary becomes final, section 1128A(h) directs the Secretary to notify certain specified appropriate State or local agencies, organizations, and associations and to provide the reasons for the penalty. We propose to add the public generally, in order to make the information available to anyone who must make decisions with respect to covered entities. For instance, 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 industry, while information about the imposition of a civil money penalty for violation of the Transactions Rule or other HIPAA rules could be of

interest to a covered entity's trading partners. The regulatory language would provide for notification in such manner as the Secretary deems appropriate. Posting to an HHS web site and/or the periodic publication of a notice in the *Federal Register* are among the methods which the Secretary is considering using for the efficient dissemination of such information. These methods would avoid the need for the Secretary to determine which entities, among a potentially large universe, should be notified and would also permit the general public served by covered entities upon whom civil money penalties have been imposed to be apprised of this fact, where that information is of interest to them."

Comment: Would this include anything identified that has been referred to the Department of Justice or only civil monetary penalties? We request additional clarification in the final rule. We believe that it should not include potential violations that were referred to the Department of Justice for additional investigation and disposition.

D. 6. Section 160.512 -- Pre-hearing Conferences (page 20242)

"Proposed 160.512 would revise paragraph (a) to establish a minimum amount of notice (not less than 14 business days) that must be provided to the parties in the scheduling of pre-hearing conferences."

Comment: This time frame is inadequate to get all necessary parties involved to prepare a response. We ask that the Secretary consider extending the time frame to 25 business days.

D. 12. Section 160.542 -- The Record (page 20243)

"This section is 160.560 of the April 17, 2003 interim final rule. Since the section provides that the record of the proceedings be transcribed, we propose to add to paragraph (a) of this section a requirement that the cost of transcription of the record be borne equally by the parties, in the interest of fairness."

Comment: We believe that this fee should be assessed at the end of the investigation and assumed by the responsible party based on the outcome of the investigation.

D. 15. Section 160.552 -- Harmless Error (page 20243)

"Proposed 160.552 is new. It would adopt the "harmless error" rule that applies generally to civil litigation in federal courts. The provision provides, in general, that the ALJ and the Board at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties. It is modeled on Rule 61, F.R.C.P., and on 1005.23 of the OIG regulations. In its application, it would further promote the efficient resolution of cases where the proposed imposition of a civil money penalty is challenged."

Comment: Further guidance and clarification is needed on this section.

V. Response to Public Comments

G. (page 20245)

Response: In any event, nothing in the Privacy Rule precludes covered entities from retaining documents for a longer period than 164.530(j)(2) requires, if they wish to do so."

Comment: We believe that a CE should not be penalized if they chose not to retain documents for a period longer than the 6-year requirement. See earlier comments. Would a CE be penalized for document destruction that was done in accordance with the 6-year retention, but then was requested as a part of an investigation?

H. (page 20245)

Response: Like 160.514, proposed 160.420 does not identify the person(s) to whom the notice of proposed determination should be addressed, nor do we think it is necessary or feasible to do so. Rule 4, which applies under section 1128A(c), establishes who may be

served and applies without need for further regulatory action. Because the size and other organizational circumstances of covered entities vary greatly, a rule that further limited or defined who must be served would most likely be inappropriate for some covered entities.”

Comment: Correspondence should be directed to the Privacy Official. The HIPAA Privacy Rule requires a covered entity to have this position, regardless of size. This will enhance timely communication to appropriate persons within the organization.

NCHICA has previously suggested to OCR that CEs might voluntarily submit to DHHS a specific office and address for service of complaints or other official documents related to an investigation. This is particularly important in larger organizations where ambiguously addressed letters may not reach the appropriate office in a timely manner.

Thank you for considering our comments and we look forward to the final rule after all comments have been considered.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. Holt Anderson', with a stylized flourish at the end.

W. Holt Anderson
Executive Director
NCHICA