

September 13, 2010

Department of Health and Human Services  
Office of Civil Rights  
200 Independence Avenue SW  
Room 509-F  
Washington DC 20201

Re: RIN: 0991-AB57- Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act

Dear Ladies and Gentlemen,

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide comment to the Department of Health and Human Services (HHS) regarding RIN 0991-AB57 Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act. ASN is a not-for-profit organization of 11,000 scientists and physicians (nephrologists) dedicated to cutting-edge medical research and delivery of the highest quality therapies to patients with kidney disease. Foremost among ASN's concerns is the continued support of basic, translational, and clinical kidney disease research.

ASN recognizes the vital importance of protecting individual medical information through HIPAA privacy standards. HIPAA provides an essential bulwark in guarding private information from unauthorized use. The respect for privacy standards in medical research studies is essential for public trust in the research community and has historically been upheld in research regulations such as the Common Rule. As such, it is of utmost importance that investigators hold themselves to the strictest standard of adherence to HIPAA.

However, HIPAA regulations at times place an administrative and scientific burden on robust and timely research. The changes planned in the Proposed Rule would help alleviate existing HIPAA related challenges while ensuring that patient privacy continues to be safeguarded. The society thanks HHS for this proposal, and offers the following specific comments.

**Compound Authorization, page 40893:**

ASN applauds HHS' proposal to eliminate dual consent forms for conditional and unconditional authorizations by allowing covered entities in research-related scenarios to use a compound authorization form. Allowing for compound authorizations will help streamline collection of permissions while allowing patients to opt out of situations they may be uncomfortable with under unconditional usage. ASN agrees with HHS that to "combine research authorizations would streamline the process for obtaining an individual's authorization for research and...make the documentation responsibilities of these covered entities more manageable." As noted in the Proposed Rule, clinical trials often involve thousands of patients and take place over the course of many years; consequently collecting and storing dual authorizations is incredibly burdensome and often confusing to patient participants.

Furthermore, ASN appreciates and supports the proposal to allow covered entities flexibility in designing a compound authorization form. The Common Rule already requires separate discussion/headings in an informed consent document. Therefore, allowing HIPAA authorization as a separate heading in the informed consent will be consistent with current practices and will not place a burden on researchers.

**Future Research, page 40893:**

ASN supports HHS' proposal to interpret the Privacy Rule as allowing authorizations to cover use of medical specimens for future research activities involving databases or repositories in general--rather than requiring researchers to specifically cite the intended research purpose at the time of authorization collection. New methodologies in research such as proteomics, genetic studies and array data require analysis of large numbers of specimens. The future use of this information--as well as yet-to-be-discovered technologies that would enable unraveling of existing scientific mysteries--cannot be accurately predicted. Because medical research is a quickly evolving field, there may come a time when allowing for easier access to specimens for mental or genetic research is prudent. Allowing for general permission of future usage is a proactive approach to future research and health discoveries.

HHS proposes three options for easing this interpretation (40894). ASN encourages HHS to adopt option number 1, which would permit authorization for uses and disclosures of Protected Health Information (PHI) for future research purposes as described in the proposal. Under option 1, all research would be thoroughly reviewed by an Institutional Review Board (IRB) as required by the Common Rule. IRBs are well equipped to individualize specific research requests and interpret the appropriateness based on the community and population involved, current acceptance by communities for release of specific information, and the scientific rationale presented by the investigator. This approach would ensure that study participants have the option and may elect to authorize future research while ensuring the consent/authorization adequately describes the risks and benefits to study participants. Option 1 would permit much-needed flexibility to accommodate changing research methodologies and societal interpretation of the risks associated with evolving science; as such ASN strongly encourages HHS to select this option.

For both dual and compound authorizations, ASN requests clarification on who would be considered a covered entity under the exceptions. Based on the information presented in the proposal, it seems that a 'covered entity' would be the primary research institution where the Principal Investigator resides. Under the Common Rule, the Principal Investigator is currently responsible for the integrity of research data, which includes safeguarding the confidentiality of such data. Thus, HIPAA should align with the Common Rule in defining the covered entity.

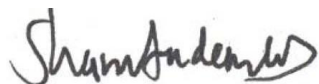
**Disclosure of Protected Health Information for Research Purposes, page 40891:**

The society supports the proposed exception allowing financial remuneration for disclosure of protected health information for research purposes. As stated in the proposed Rule, preparation and

transmission of this information incurs a cost. Financial remuneration to cover this expense is both fair and prudent, especially as it may encourage active engagement and cooperation of dialysis facilities with researchers. ASN recommends important costs such as data and specimen collection, preparation, storage and delivery costs be included in the definition of “reasonable costs.”

On behalf of ASN, thank you for your willingness to consider our comments for the proposed rule on modifications to the HIPAA Privacy, Security, and Enforcement Rules under the Health Information Technology for Economic and Clinical Health Act. We believe that our recommendations will prove helpful in formulating policies that continue to protect sensitive individual medical information while ensuring necessary data remains available to researchers through an efficient and fair process. To discuss ASN’s comments, please contact ASN director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at [psmedberg@asn-online.org](mailto:psmedberg@asn-online.org).

Sincerely,



Sharon Anderson, MD, FASN  
President, American Society of Nephrology