



January 14, 2013

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Patriots Plaza III
355 E Street, SW.
Washington, DC 20201

Re: Stage 3 Definition of Meaningful Use of Electronic Health Records

Dear Sir or Madam:

The Confidentiality Coalition respectfully submits these comments in connection with the Request for Comment regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (published in the Federal Register on November 26, 2012) (the "Request for Comment").

Background

The Confidentiality Coalition is composed of a broad group of hospitals, medical teaching colleges, health plans, pharmaceutical companies, medical device manufacturers, vendors of electronic health records, biotech firms, laboratories, employers, health product distributors, pharmacies, pharmacy benefit managers, health information and research organizations, patient groups, and others¹ founded to advance effective patient confidentiality protections.

The Coalition's mission is to advocate policies and practices that safeguard the privacy of patients and healthcare consumers while, at the same time, enabling the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions. The Confidentiality Coalition is committed to ensuring that consumers and thought leaders are aware of the privacy protections that are currently in place. And, as healthcare providers make the transition to a nationwide, interoperable system of electronic health information, the Confidentiality Coalition members believe it is essential to replace the current mosaic of sometimes conflicting state healthcare privacy laws, rules, and guidelines with a strong, comprehensive national confidentiality standard for healthcare information.

In this response, we offer comments on limited aspects of the Request for Comment, related specifically to privacy and security issues.

¹ This comment letter reflects a consensus view of our members. It does not necessarily reflect the point of view of each member of the Coalition.

The Confidentiality Coalition wholeheartedly supports the value of electronic health records and the related development of a nationwide electronic health information exchange to facilitate better patient care. We also recognize the importance of ensuring appropriate privacy and security protections for these records. The Request for Comment covers a wide range of areas related to the meaningful use principle for electronic health records. While many of our members will be developing approaches to electronic health records that utilize these meaningful use principles (and may submit their own comments on these other aspects of the proposal), our comments as a Coalition focus specifically and exclusively on the privacy and security aspects of the Request for Comment.

In particular, we have two specific comments and concerns about the proposal. First, the Coalition believes that the HIPAA Security Rule provides appropriate information security standards for the development of electronic health records, and that there is no need for additional requirements that go beyond these HIPAA provisions. Second, we do not believe that it is appropriate to modify the requirements for electronic health records based on the proposed changes to the HIPAA “accounting of disclosures” rule because these proposals are exceedingly problematic and have not been finalized in any way. Therefore, it is premature and inappropriate to implement any requirements for accounting of disclosures or related audit trail components based on these highly criticized draft proposals.

Comments

- Security Standards for EHRs (ID # PSTT04)

The Request for Comment seeks comment on security risk issues that should be subject to a Meaningful Use attestation. We do not object to guidance or advice issued by the HHS Office of Civil Rights related to the HIPAA Security Rule. We also do not object, in the appropriate context, if ONC issues its own guidance about recommendations for steps related to security risk analysis or other aspects of the HIPAA Security Rule. However, we do not believe that ONC should include additional security steps as a component of a meaningful use attestation. The HIPAA Security Rule will apply to any entity seeking meaningful use incentives (as a HIPAA covered entity). These standards are thorough and complete in identifying how healthcare entities should approach information security issues and the required steps that need to be taken across a covered entity’s business. The Security Rule requires specific risk management steps, including the identification of specific risks and the development of appropriate standards to mitigate these risks. The obligation to undertake these steps is a required component of HIPAA compliance for every covered entity (and shortly will be, as well, for all business associates).

The Request for Comment utilizes the idea of training as a potential element of an attestation, based on HIPAA compliance reviews that identified certain weaknesses in compliance related to training. While training is an important aspect of any kind of compliance, we do not see a value in singling out any particular element of the HIPAA Security Rule as deserving more attention than others or imposing additional obligations related to any particular requirements, even if compliance problems have been identified in the past. Covered entities and their business associates have an obligation to comply with these provisions, as applicable to their overall business. Responding to identified gaps – even gaps in others – is a critical component of a

compliance strategy. This HIPAA standard, therefore, with its risk-focused approach, is sufficient to address the full range of information security concerns raised by electronic health records. There is no need for additional, supplemental or highlighted requirements as part of any particular aspect of the operation of a health care entity's business.

Moreover, HHS (through the Office of Civil Rights) is in the midst of implementing the required changes to HIPAA from the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Congress has spoken on its desired changes to the HIPAA structure, and we see no basis at this time to go beyond Congressional intent (which has not yet even been implemented in full) to impose a broader set of changes. If ONC does in fact propose new privacy and security standards that affect electronic health records or health information exchange (HIE) activity more broadly, it should delay any such efforts until HITECH has been finalized and implemented.

- Accounting for Disclosures (ID# PSTT05-08)

ONC also seeks comments on potential new standards for accounting for disclosures. We see no reasonable basis for imposing any additional standards on EHRs related to accounting for disclosures. While not specifically identifying the HHS proposal under HIPAA related to the accounting rule in its Request for Comment, this proposed rule appears to be the basis for ONC's questions (and earlier had served as the basis for ONC's proposal related to certification standards for accounting of disclosures). In its similar and earlier NPRM related to 2014 certification standards, the Department asked for comment on whether it should adopt a revised certification criterion, based on the separate HHS proposal related to the HIPAA "accounting of disclosures" rule. As the Coalition made clear in its earlier comments to that NPRM, the Coalition believes that no new requirements of any kind should be implemented based on the proposed changes to the HIPAA accounting rule. There was widespread and virtually universal concern about the HHS proposal, as defined by the comments to the proposed changes to the "accounting of disclosures" rule. Moreover, we believe that the proposed changes to the HIPAA accounting rule ignored the fact that the HITECH statute (P.L. 111-5) requires HHS to balance the patient's interest in learning how his or her information is disclosed in a way that leverages readily-available technology and does not overly burden covered entities and their business associates. Therefore, because of these substantial concerns with the proposed changes and the uncertainty as to any ultimate result, we believe it is inappropriate to make any changes at all to the meaningful use standards that are based on the proposed changes to the HIPAA accounting of disclosures rule.

The Coalition submitted a substantial comment letter to the Department on the proposed rule related to the accounting of disclosures requirement (attached as Exhibit 2 to this comment letter). Our comments were consistent with hundreds of others submitted by an array of stakeholders, who almost universally criticized the proposed rule and recommended that the rule be withdrawn. Without restating all of the detail of our accounting of disclosures comment letter, we include below a brief excerpt from these comments. As we indicated in our letter,

The Confidentiality Coalition has submitted comments on a variety of proposed HITECH and HIPAA regulations over the past several years. In many of those comments, we have applauded the HHS proposal, and have made minor suggestions related to some of the details of the

proposal. We appreciate the Department's overall efforts – both during the original HIPAA rulemakings and as part of the HITECH process – to develop and implement regulations that appropriately balance individual interests in privacy and security with the imposition of reasonable burdens on the healthcare industry. We have appreciated the Department's recognition of practical issues that need to be balanced in developing appropriate regulations.

This set of comments is different. We believe that the proposed rule – particularly the requirement for a new “access report” – is unworkable. We believe it reflects both an inaccurate and unreasonable interpretation of the HIPAA Security Rule and insufficient knowledge of the capabilities of the applicable technology in the healthcare industry. While some of the detail points we address below could serve to moderate the adverse impact of this proposed rule, we believe strongly that HHS should completely re-evaluate this entire proposal for a HIPAA access report right. Collectively, the members of the Confidentiality Coalition believe strongly in the protection of patient privacy interests. We have supported many of the provisions of the HIPAA Privacy and Security Rules as reasonable and appropriate protections for privacy with a balanced burden on covered entities and business associates. However, we believe that this proposed access report will provide little benefit to individuals, that the primary interests identified by the Department for individuals can be served in much narrower and more satisfactory ways, and that this rule – if implemented as written – will require enormous new technology efforts and expenditures from virtually all entities in the healthcare industry (as well as their business partners), with substantial ongoing burden. We also believe that this access report could create realistic risks for employees who are identified in these reports, and that the reports could be used for many inappropriate purposes that are unconnected to any incidental privacy interests.

As this excerpt makes clear, we do not believe that the proposed changes to the HIPAA accounting of disclosures rule are reasonable or appropriate. In fact, if adopted, this proposal would require enormous expense and create a variety of new and complicated problems without any material enhancement of patient privacy. We believe that this accounting of disclosures proposal should be withdrawn. At a minimum, we are hopeful that the proposal will not be adopted as proposed. Therefore, it is our strong view that, in connection with the Request for Comment here, no changes should be made and no new requirements should be added to reflect anything about this proposed “accounting of disclosures” rule. It is our hope that the accounting of disclosures proposed rule will be eliminated, and that the Department will move forward with a new proposal for comment that reflects a better understanding of both the current technological environment and a more realistic balance between burden and benefit. Until that time, however, we do not believe that any changes should be made to existing meaningful use standards to reflect anything about this proposed accounting of disclosures rule.

Conclusion

The Confidentiality Coalition appreciates ONC's efforts to implement appropriate standards for the Stage 3 meaningful use effort. In connection with the limited number of privacy and security proposals, the Coalition believes that ONC should not implement additional security requirements beyond the HIPAA standard, and that ONC should not revise the standards based on a flawed proposal to change the HIPAA accounting rule

The Confidentiality Coalition appreciates this opportunity to comment on this Request for Comment. Please contact Tina Grande, Senior Vice President for Policy at the Healthcare Leadership Council, with any questions about this letter at tgrande@hlc.org or 202.452.8700.

Sincerely,



Mary R. Grealy
President, Healthcare Leadership Council
On Behalf of the Confidentiality Coalition

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