



Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

July 25, 2011

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Mostashari:

The HIT Policy Committee (Committee) gave the following broad charge to the Privacy & Security Tiger Team (Tiger Team):

Broad Charge for the Privacy & Security Tiger Team:

The Tiger Team is charged with making short-term and long-term recommendations to the Health Information Technology Policy Committee (HITPC) on privacy and security policies and practices that will help build public trust in health information technology and electronic HIE, and enable their appropriate use to improve healthcare quality and efficiency, particularly as related to ARRA and the Affordable Care Act (ACA) which mandates a number of duties to the ONC relative to privacy and security.

This letter provides recommendations to the Department of Health and Human Services (HHS) on the issue of amendments/corrections to electronic medical records. On July 6, 2011, the Tiger Team reported on and discussed its findings with the Committee, which subsequently approved the recommendations as outlined below.

Tiger Team Recommendations on Amendments/Corrections

In its Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information,¹ the Office of the National Coordinator for Health IT (ONC) adopted the following principle on “Correction”:

Individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information (IIHI), and to have erroneous information corrected or to have a dispute documented if their requests are denied.

¹ The Framework was first released by ONC in December 2008 and has been subsequently included in the ONC Health IT Strategic Plan.

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule already sets forth specific requirements that covered entities must follow in responding to patients' requests for corrections or amendments to the entities' records. In an appendix to these recommendations, we have included a summary of the relevant provisions of the Privacy Rule. Briefly, in some circumstances covered entities face obligations to make amendments to their records or to append notes or other information from the patient and the covered entity regarding disputed information in the record; they also may be required to communicate amendments or other appended information about disputed data to other entities that may have previously received the data.

As medical information is increasingly exchanged in electronic form and made more available to patients, increasing numbers of patients may take advantage of their rights to request an amendment under the HIPAA Privacy Rule. Stakeholders have raised concerns about whether electronic health record (EHR) systems have the technical capability to help covered entities comply with these HIPAA requirements. In addition, the HIT Policy Committee's (HITPC) Privacy & Security Tiger Team (Tiger Team) considered issues relating to data integrity and quality when a clinician corrects errors that were not reported by the patient or needs to communicate updates to a patient's information. The Tiger Team considered these issues and makes the following recommendations:

- 1. Certified EHR Technology should have the capability in Meaningful Use Stage 2 to support amendments to health information, and in particular to support a provider's compliance with HIPAA obligations to respond to patient requests for amendments. Specifically, the systems should make it technically possible for providers to:**
 - a. Make amendments to a patient's health information in a way that is consistent with the entity's obligations with respect to the legal medical record (i.e., there should be the ability to access/view the original data and to identify any changes to it).**
 - b. Append information from the patient and any rebuttal from the entity regarding disputed data.**

- 2. Certified EHR Technology should have the ability by Meaningful Use Stage 3 to transmit amendments, updates or appended information to other providers to whom the data in question has been previously transmitted.**

The HIT Standards Committee (HITSC) should recommend any necessary standards, implementation specifications, and certification criteria to accomplish the foregoing recommendations, which should include the ability to incorporate amendments or updates transmitted from other entities. The Tiger Team recommends that the technical capabilities be initially kept as simple as possible and evolve over time to greater complexity, including potentially greater standardization and automation.

The HIPAA Privacy Rule obligations to amend health information (or append information about disputed data) apply only when a patient requests an amendment to health information. The Tiger Team also considered whether to impose affirmative obligations (such as through the

conditions of participation for the Nationwide Health Information Network or NwHIN) on providers to inform other entities about errors that are surfaced by record holders and not in response to a particular patient request.

The Tiger Team determined that it was not possible to establish one set of directives governing when self-discovered errors and amendments need to be forwarded to other providers given the range of different errors that could occur (some of little consequence for patients) and the potential difficulty of differentiating between a true error and a difference of medical opinion. The Tiger Team decided that providers' existing ethical and legal obligations were sufficient to motivate them to use appropriate professional judgment regarding when to inform any known or potential recipients of amendments to health data. The Tiger Team also thought that if certified EHR systems had the technical capability to make and propagate amendments, providers would have the tools they need to communicate amendments not only in response to a patient request but also in response to a provider's own discovery of an error or need to update.

The Tiger Team also considered whether health information exchange organizations (or HIOs) should have obligations to correct errors they may be responsible for and obligations to transmit amendments or updates (whether generated by the HIO or one of its participating entities) to affected providers. The Tiger Team specifically seeks input from the HIT Policy Committee on this issue and will be doing some research on existing HIO policies prior to developing any recommendations on this issue.

We appreciate the opportunity to provide these recommendations on amendments/corrections to electronic medical records, and look forward to discussing next steps.

Sincerely yours,

/s/

Paul Tang
Vice Chair, HIT Policy Committee

Appendix – Summary of Provisions of HIPAA Privacy Rule Dealing with Patient Requests for Amendments (45 C.F.R. 164.526)

- Individuals have the right to ask a covered entity to amend PHI in a “designated record set”; this covers demographic and clinical information in an EHR.
- A covered entity may deny the request if that entity didn't create the information, unless the originator of the information is not available to act on the request. (Thus, individuals are not required to go to the source - but if they go to downstream entity, that entity is not necessarily obligated to make a correction unless the “originator” is not available.)
- Covered entities may also deny the request if it's the type of PHI that the patient doesn't have the right to access, or if the covered entity believes the information is accurate and complete (i.e., the entity disputes the need for a correction).
- Covered entities may require requests for amendment to be in writing and provide a reason for the request; they have to act on the amendment no later than 60 days following the receipt of the request (although this can be extended for up to 30 additional days if they give a reason for the delay and a date for completion).
- If a covered entity agrees to the amendment, it must:
 - At a minimum, identify the records affected by the amendment and "append" or "otherwise provide a link to the location of" the amendment.
 - Inform the individual that the amendment is accepted and get the individual's identification of and agreement to have the covered entity notify the relevant entities that should receive the amendment.
 - Make reasonable efforts to inform and provide the amendment within a reasonable time to (i) the persons identified by the individual as needing the amendment; and (ii) persons, including BAs, that the entity knows have the PHI to be amended and "that may have relied or could foreseeably rely, on the information to the detriment of the individual."
- If the covered entity denies the amendment, the entity must:
 - Provide the individual with a written denial that includes the basis for the denial plus information of the individual's right to submit a written statement of disagreement
 - If the individual chooses not to submit such a statement, they can request that the covered entity provide the request for amendment and the denial with any future disclosures of the disputed PHI - and the covered entity has to inform the individual of this right. (The covered entity only has to do this if the individual requests that this action be taken.)
 - If the individual submits the written statement of disagreement, the covered entity may prepare a rebuttal, a copy of which must go to the individual.
 - With respect to the PHI in dispute, the covered entity must append or link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement (if any), and the entity's rebuttal (if any) to the

information and include it in future disclosures (the entity also has the option of instead appending an accurate summary of this information).

- A covered entity data recipient that receives notice from a covered entity that it granted an individual's request for amendment must make the amendment to the information in its records.