



Discussion Paper: Patient Amendments and Corrections to Protected Health Information

Background:

- As medical information is increasingly exchanged in electronic form and made available to patients, more patients may take advantage of their rights under the HIPAA Privacy rule to request amendments to their own records. As a result, stakeholders have raised concerns as to whether electronic health record (EHR) systems have the capabilities to deal with these requirements.
- Requests for amendments or other changes from sources other than the patient may result in the need to correct the medical record. Corrections to the record need to be carefully documented to preserve the integrity of the record. In addition, in a highly networked environment, the risk exists that inaccurate PHI could be quickly proliferated among multiple entities. However, HIPAA does not specifically address how entities are to address correction.

Definitions:

- An *amendment* is any change requested by an individual to their PHI or a record about them to ensure accuracy and completeness. The process for requesting and responding to amendments is outlined in the HIPAA Privacy Rule. (Note: This term is not specifically defined in the Privacy Rule, but this definition is derived from its provisions)
- *Other changes* are any potential change in a medical record identified by an individual or entity other the patient or their personal representative. The HIPAA Privacy Rule does not specifically address these changes.
- Amendments and other changes may result in (1) *corrections*, which replace erroneous information with accurate information and (2) *addendums*, which add information to the record to make it more complete. These actions are distinct from *updates*, which may routinely occur because of changes in patient data over time.

How to Use This Document

The following sections provide principles around the life cycle of requests for amendments and other changes, along with existing requirements and additional “strawman” requirements for further Tiger Team consideration. Existing HIPAA requirements are *grayed*. Additional “strawman” requirements for consideration are in **bold**.

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Principles for Patient Requests for Amendment

1. Individuals have the right to have a covered entity amend their PHI if it is inaccurate or incomplete.
 - Patients have the right to have covered entities amend their PHI in a designated record¹ set when that information is inaccurate or incomplete.
 - An individual's personal representative may be able to request an amendment to the individual's PHI or record, depending on the scope of authority granted to them.
2. All covered entities are responsible for responding to requests for amendment.
 - Covered entities should have procedures in place describing how individuals can request amendments to their PHI.
 - The covered entity may require individuals to make a request for amendment in writing and to provide a reason to support a requested amendment, provided it informs individuals in advance of this requirement.
 - If the covered entity grants the requested amendment, it must inform the individual that the amendment has been accepted and obtain the individual's identification and agreement to notify other relevant entities.
 - A covered entity may deny a request if the information (1) was not created by the covered entity, (2) is not part of the designated record set, (3) would not be available to the individual under access requirements,² and/or (4) is accurate and complete.
 - If the covered entity denies the request, it must provide the individual with a timely denial in writing.
 - **Generally, clinicians are responsible for determining whether a correction is needed to clinical information in a medical record.**
3. The covered entity that is the source of the original entry is responsible for making determinations about changes—corrections and addendums—resulting from requests for amendments.
 - **If the request is granted by an entity, the specific person responsible for making corrections will vary according to the type of PHI involved.**

¹ A designated records set is that group of records maintained by or for a covered entity that is used, in whole or part, to make decisions about individuals, or that is a provider's medical and billing records about individual or a health plan's enrolment, payment, claims adjudication, and case of medical management records systems.

² The Privacy Rule exempts the following types of information from access requirements: psychotherapy notes, information compiled for legal proceedings, laboratory results to which the Clinical Laboratory Improvement Act prohibits access, or information held by certain research laboratories.

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- A covered entity that is informed of an amendment by another covered entity must amend the PHI, in the same fashion as if the individual had requested an amendment.
4. Individuals should have avenues of redress if they disagree with a covered entity's denial of an amendment.
 - The covered entity must permit the individual to submit a written statement disagreeing with the denial and the basis for disagreement.
 - An individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the PHI
 - The covered entity may prepare a written rebuttal to the individual's statement of disagreement.
 - The covered entity must also inform the individual as to how to file a complaint.
 5. When sharing PHI, covered entities should inform recipients of any information that is disputed by the individual.
 - If the individual has submitted a statement of disagreement, the covered entity must append this information or provide an accurate summary of such information.
 - If the individual has not submitted a statement of disagreement, the covered entity must append the request for amendment and the denial to disclosures, if specifically requested by the individual
 6. Consistent with existing technological capabilities, electronic health record (EHR) systems should provide the ability to amend PHI consistent with HIPAA

Questions: To what extent do EHRs have the technical capability to perform these functions? What are the limitations? What role should EHR certification play in establishing technical capabilities?

- **The EHR system should have the ability to append disputed data with the patient's statement of disagreement or the request for amendment and denial (if requested by the individual)**
- **The EHR system should have the ability to identify the other entities with whom PHI has been shared electronically.**

Questions: To what extent will entities have the capability of identifying with whom the information has been shared? Does this recommendation need to have a caveat about upcoming accounting of disclosure regulations?

- **Regarding corrections to PHI:**

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- EHR systems should allow corrections, have the ability to track corrections, and identify that an original entry has been changed.
 - The original entry should be viewable, along with a date/time stamp, person making the change, and reasons for the change.
7. Covered entities should inform and provide an amendment to other individuals and organizations with whom the PHI was shared.

Questions: To what extent do recipients of PHI have a responsibility to notify other entities of amendments in a highly networked environment? How, if at all, can any such notification requirement be balanced with the need to avoid “notification overload?”

- The covered entity must make reasonable efforts to inform and provide an 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."
- **A covered entity data recipient that receives notice from a covered entity of amended PHI, must notify that covered entity of additional recipients of the PHI.**

Questions: Should such notice always be required? Should we create a notification threshold – such as likelihood of impact on care of the patient?

- **A entity data recipient that receives notice from a covered entity (source) of amended PHI, must make (and have the capacity in their EHR to make) a similar amendment in their own record.**

Principles for Other Changes to PHI in Medical Records

1. Any individual or organization with access to PHI has a responsibility to identify potentially inaccurate and incomplete PHI and notify the source (entity or organization) of that information of the potential inaccuracy/data gap in any clinical data.
2. Any individual or organization with access to PHI should have written procedures in place to address responsibility with regard to identifying PHI (to the source entity) that may need to be corrected or added to and a process for evaluating and documenting those changes.
3. When notified of the need for a potential change to PHI, providers should act promptly to assess whether a correction or addendum is appropriate.

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4. **The provider entity that is the source of the original entry is responsible for making changes to correct errors and ensure completeness.**
 - **The specific individual within the provider organization responsible for making the change may vary depending on the type of PHI involved**
5. **Consistent with existing technological capabilities, electronic health record (EHR) systems should provide the ability to make corrections to PHI, in accordance with industry standards. (requirements below are the same as those recommended above re: patient requested corrections)**
 - **EHR systems should allow corrections, have the ability to track corrections, and identify that an original entry has been changed.**
 - **The original entry should be viewable, along with a date/time stamp, person making the change, and reasons for the change.**
 - **The EHR system should have the ability to suppress the original entry that was corrected, but use a flag to note that it exists.**
6. **Covered entities should provide an alert or the corrected PHI to other individuals and organizations with whom the PHI was shared. (Note: Approach may be dependent on exchange architecture employed.)**

Question: Again, what, if any, threshold should be established for providing alerts and/or corrected information to others with whom the information was shared?

- **The provider must make reasonable efforts to provide an alert or the corrected PHI within a reasonable time to persons, including BAs, that the entity knows have the PHI to be corrected and "that may have relied or could foreseeably rely, on the information to the detriment of the individual."**