Implementation Specifications under **Federal Regulation 45 CFR § 164.526 - Amendment of protected health information**.

**GDPR regulations** concerning patient Rights to Rectification

HIPAA and GDPR are very similar in their regulations except for the period of time to respond to the initial request for corrections and the preference in GDPR for a means for patient requests to be made electronically. Contents of communication is nearly identical and are met by the listings below.

**Patient requests covered entity amend their medical record**

[recommended contents: patient identification (name, dob, ?), identification of incorrect records, correction to be made, reason for correction, list of people/orgs that need to be identified, request for copy of updated record, contact information, ?]

**HIPAA: The covered entity must respond within 60 days**, which may include an extension of 30 days with a reason for the delay and date they will complete its action on the request.

**GDPR: The covered entity must respond within 1 month**, which may include an extension of 2 months if the request is complex or you have received a number of requests from the individual.

**Entity accepting amendment request**

[Contents: identification of affected records, identification of recipients who received corrected data, ?]

**Entity denying amendment request**

[Contents: denial of the request with reason for denial, individual’s right to submit a statement of disagreement, a description of how the patient can file a complaint with the entity.]
**Entity denying amendment request**

Patient sends a written statement disagreeing with the denial and desire to have disputed amendment identified in all subsequent disclosure of disputed PHI.

**Entity denying amendment request**

Covered entity may prepare a written rebuttal to the individual's statement of disagreement.

**Future Disclosures:**

CE must include an accurate summary of dispute with any subsequent disclosure of the PHI to which the disagreement relates.

**HIPAA Implementation specifications: Accepting the amendment.**

If the covered entity grants the requested amendment, it must:

- **Making the amendment:** Identify the records that are affected by the amendment and appending or providing a link to the location of the amendment.

- **Informing the individual:** Timely inform the individual that the amendment is accepted and obtaining the individual’s identification and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared.

- **Informing others:** Make reasonable efforts to inform and provide the amendment within a reasonable time to:
  - Persons identified by the individual as having reviewed the PHI and needing amendment
  - Persons and business associates, that the covered entity knows have the PHI that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

**Implementation specifications: Denying the amendment.**
If the covered entity denies the requested amendment, it must:

- **Denial:** Provide the individual with a timely, written denial and must use plain language and contain:
  - The basis for the denial
  - The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement
  - A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and
  - A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.530 or to the Secretary pursuant to the procedures established in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

- **Statement of disagreement:** The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement.

- **Rebuttal statement:** The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.

- **Recordkeeping.** The covered entity must identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise 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 covered entity's rebuttal, if any, to the designated record set.

- **Future disclosures.**
  - If a statement of disagreement has been submitted by the individual, the covered entity must include an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.
  - If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action.
  - When a subsequent disclosure is made using a standard transaction that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the required material to the recipient of the standard transaction.