

45 CFR 164.316: Policies And Procedures And Documentation Requirements

A. A covered entity must, in accordance with § 164.306:

1. *Standard:* Policies and procedures. Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(B-2). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

2. *Standard:* Documentation.

a. Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

b. If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

b. *Implementation specifications:*

- Time limit (Required). Retain the documentation required by paragraph (2) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

- Availability (Required). Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

- Updates (Required). Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.