

- Moved proposed § 142.308(b)(3)(ix), “Testing and revision,” to § 164.310(a)(2)(iii) and renamed as “Access control and validation procedures.”

- Moved proposed § 142.308(b)(4), “Policy and guidelines on workstation use,” to § 164.310(b) and renamed as “Workstation use.”

- Moved proposed § 142.308(b)(5), “Secure work station location,” to § 164.310(c) and renamed as “Workstation security.”

- Removed proposed § 142.308(b)(6), “Security awareness training,” as a separate requirement. This requirement has been incorporated under § 164.308(a)(5)(i), “Security awareness and training.”

- Combined and moved proposed § 142.308(c) and § 142.308(d), “Technical security services to guard data integrity, confidentiality and availability” and “Technical security mechanisms,” to § 164.312 and renamed as “Technical safeguards.”

- Removed proposed § 142.308(c)(1) since it is no longer pertinent.

- Moved proposed § 142.308(c)(1)(i), “Access control,” to § 164.312(a)(1).

- Moved proposed § 142.308(c)(1)(i)(A), “Procedure for emergency access,” to § 164.312(a)(2)(ii), and renamed as “Emergency access procedures.”

- Removed proposed § 142.308(c)(1)(i)(B).

- Removed proposed § 142.308(c)(1)(i)(B)(1), “Context-based access,” § 142.308(c)(1)(i)(B)(2), “Role-based access,” and

- § 142.308(c)(1)(i)(B)(3), “User-based access,” since these features were deemed too specific and were perceived as the only options permissible.

- Moved proposed § 142.308(c)(1)(i)(C), “Optional use of encryption,” to § 164.312(a)(2)(iv) and retitled “Encryption and decryption.”

- Moved proposed § 142.308(c)(1)(ii), “Audit controls,” to § 164.312(b).

- Removed proposed § 142.308(c)(1)(iii), “Authorization control,” and all implementation features (Role-based access, User-based access) since this function has been incorporated into § 164.308(a)(4), “Information access management.”

- Moved proposed § 142.308(c)(1)(iv), “Data authentication,” to § 164.312(c)(1), and retitled as “Integrity.” Reworded part of description and placed in § 164.312(c)(2), “Mechanism to authenticate data,” a new, addressable implementation specification. Removed reference to double keying.

- Moved proposed § 142.308(c)(1)(v), “Entity authentication,” to § 164.312(d)

and retitled as “Person or entity authentication.”

- Moved proposed § 142.308(c)(1)(v)(A), “Automatic logoff,” to § 164.312(a)(2)(iii).

- Moved proposed § 142.308(c)(1)(v)(B), “Unique user identification,” to § 164.312(a)(2)(i).

- Removed proposed § 142.308(c)(1)(v)(C) since text is no longer pertinent.

- Removed proposed § 142.308(c)(1)(v)(C)(2), “Password,” as too specific.

- Removed proposed § 142.308(c)(1)(v)(C)(3), “PIN,” as too specific.

- Removed proposed § 142.308(c)(1)(v)(C)(4), “Telephone callback,” as too specific.

- Removed proposed § 142.308(c)(1)(v)(C)(5), “Token,” as too specific.

- Removed proposed § 142.308(c)(2), as no longer relevant.

- Moved proposed § 142.308(d)(1), “Communications or network controls,” to § 164.312(e)(1) and renamed as “Transmission security.”

- Removed proposed § 142.308(d)(1)(i), since it is no longer pertinent.

- Moved proposed § 142.308(d)(1)(i)(A), “Integrity controls,” to § 164.312(e)(2)(i) and reworded for clarity.

- Removed proposed § 142.308(d)(1)(i)(B), “Message authentication,” since this subject is now covered under § 164.312(e)(2)(i), “Integrity controls.”

- Removed proposed § 142.308(d)(1)(ii) text since it is no longer pertinent.

- Removed proposed § 142.308(d)(1)(ii)(A), “Access controls.”

- Moved proposed § 142.308(d)(1)(ii)(B), “Encryption,” to § 164.312(e)(2)(ii) and reworded to enhance flexibility and scalability.

- Removed proposed § 142.308(d)(2) text regarding: “Network controls,” and all implementation features (“Alarm,” “Audio trail,” “Entity authentication,” “Event reporting”).

- Removed proposed § 142.310, “Electronic signature,” and all subheadings. This section will be issued as a separate future regulation.

- Moved proposed § 142.310 “Electronic signature Standard,” to § 164.310. Where this section was proposed to contain the electronic signature standard, it now encompasses the “Physical safeguards.”

- Moved proposed § 142.312, “Effective date of the implementation of the security and electronic signature

standards,” to § 164.318 and retitled as “Compliance dates for the initial implementation of the security standards.” Reworded and retitled subsections.

- Added § 164.105, “Organizational requirements,” with two standards, “Health care component and “Affiliated covered entities” with related implementation specifications.

- Added § 164.310(d)(2)(ii), “Media re-use procedures,” implementation specification.

- Added § 164.312, “Technical safeguards,” encompassing the combined technical services and technical mechanisms standards (proposed § 142.308(c) and (d)).

- Added § 164.314, “Organizational requirements.”

- Added § 164.314(a)(1), “Business associate contracts or other arrangements” standard and related implementation specifications.

- Added § 164.314(b)(1), “Requirements for group health plans” standard and related implementation specifications.

- Added § 164.316, “Policies and procedures and documentation requirements.”

- Added § 164.316(a), “Policies and procedures” standard.

- Added § 164.316(b)(1), “Documentation” standard and related implementation specifications.

- Added § 164.318, “Compliance dates for the initial implementation of the security standards.”

- Renamed Addendum 1 as Appendix A.

- Removed Addendum 2. Definitions of terms used in this final rule are now incorporated into § 164.103 and § 164.304, or within the rule itself.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.