

§ 164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, a waiver of informed consent by an IRB, or a waiver of authorization in accordance with § 164.512(i)(1)(i).

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in § 164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research;

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research; or

(4) A waiver of authorization in accordance with § 164.512(i)(1)(i).

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this part, a covered entity, or business associate with respect to a subcontractor, may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), only in accordance with paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance*—(1) *Qualification*. Notwithstanding other sections of this part, a covered entity, or business associate with respect to a subcontractor, is deemed to be in compliance with the documentation and contract requirements of §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to January 25, 2013, such covered entity, or business associate with respect to a subcontractor, has entered into and is operating pursuant to a written contract or other written arrangement with the business associate that complies with the applicable provisions of § 164.314(a) or § 164.504(e) that were in effect on such date; and

(ii) The contract or other arrangement is not renewed or modified from March 26, 2013, until September 23, 2013.

(2) *Limited deemed compliance period*. A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after September 23, 2013; or

(ii) September 22, 2014.

(3) *Covered entity responsibilities*. Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

(f) *Effect of prior data use agreements*. If, prior to January 25, 2013, a covered entity has entered into and is operating pursuant to a data use agreement with a recipient of a limited data set that complies with § 164.514(e), notwithstanding § 164.502(a)(5)(ii), the covered entity may continue to disclose a limited data set pursuant to such agreement in exchange for remuneration from or on behalf of the recipient of the protected health information until the earlier of:

(1) The date such agreement is renewed or modified on or after September 23, 2013; or

(2) September 22, 2014.

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