

**SELECTED HIPAA PROVISIONS  
REGARDING BUSINESS ASSOCIATES**

**I. From the Final Privacy Rules (45 C.F.R. Parts 160 and 164)**

**Definition of “business associate” as set forth in Section 160.103.**

Business associate: (1) Except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in Sec. 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in Sec. 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

**Standard for disclosures of protected health information to business associates as set forth in Section 164.502(e).**

Section 164.502(e)(1) Standard: Disclosures to business associates. (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of Sec. 164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and Sec. 164.504(e).

(2) Implementation specification: documentation. A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of Sec. 164.504(e).

**Standards for business associate contracts as set forth in Section 164.504(e).**

164.504(e)(1) Standard: Business associate contracts. (i) The contract or other arrangement between the covered entity and the business associate required by Sec. 164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in Sec. 164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) Implementation specifications: Business associate contracts. A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with Sec. 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with Sec. 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with Sec. 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) Implementation specifications: Other arrangements. (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in Sec. 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) Implementation specifications: Other requirements for contracts and other arrangements. (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate;

or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(1) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(2) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

**II. From the Notice of Proposed Rule Making (“NPRM”) (March 27, 2002 Federal Register at p. 14776)**

**Extension for business associate contracts as set forth in the proposed revision of Section 164.532(d)**

Revision to Section 164.532(d) Standard: Effect of prior contracts or other arrangements with business associates. Notwithstanding any other provisions of this subpart, a covered entity, other than a small health plan, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with 164.502(e) and 164.504(e) consistent with the requirements, and only for such time, set forth in paragraph (e) of this section.

**Model Business Associate Contract Provisions taken from the Appendix to the Preamble of the NPRM**

Model Business Associate Contract Provisions<sup>1</sup>

Definitions (alternative approaches)

Catch-all definition:

Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR §§ 160.103 and 164.501.

Examples of specific definitions:

(a) Business Associate. “Business Associate” shall mean [Insert Name of Business Associate].

(b) Covered Entity. “Covered Entity” shall mean [Insert Name of Covered Entity].

(c) Individual. “Individual” shall have the same meaning as the term Individual in 45 CFR § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

(d) Privacy Rule. “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

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<sup>1</sup> Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these model provisions and are not intended to be included in the contractual provisions.

(e) Protected Health Information. A Protected Health Information $\equiv$  shall have the same meaning as the term A protected health information $\equiv$  in 45 CFR  $\S$  164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

(f) Required By Law. A Required By Law $\equiv$  shall have the same meaning as the term A required by law $\equiv$  in 45 CFR  $\S$  164.501.

(g) Secretary. “Secretary” shall mean the Secretary of the Department of Health and Human Services or his designee.

#### Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or further disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law.

(b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Agreement.

(c) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement. [This provision may be included if it is appropriate for the Covered Entity to pass on its duty to mitigate damages by a Business Associate.]

(d) Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this Agreement.

(e) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.

(f) Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner designated by Covered Entity, to Protected Health Information in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR  $\S$  164.524. [Not necessary if Business Associate does not have protected health information in a designated record set.]

(g) Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR  $\S$  164.526 at the request of Covered Entity or an Individual, and in the time and manner designated by Covered Entity. [Not necessary if Business Associate does not have protected health information in a designated record set.]

(h) Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of, Covered Entity available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered

Entity or the Secretary, for purposes of the Secretary determining Covered Entity=s compliance with the Privacy Rule.

(i) Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR   164.528.

(j) Business Associate agrees to provide to Covered Entity or an Individual, in time and manner designated by Covered Entity, information collected in accordance with Section [Insert Section Number in Contract Where Provision (i) Appears] of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR   164.528.

#### Permitted Uses and Disclosures by Business Associate

##### General Use and Disclosure Provisions (alternative approaches)

###### Specify purposes:

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity:

[List Purposes].

###### Refer to underlying services agreement:

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in [Insert Name of Services Agreement], provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity.

##### Specific Use and Disclosure Provisions [only necessary if parties wish to allow Business Associate to engage in such activities]

(a) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

(b) Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate, provided that disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 CFR § 164.504(e)(2)(i)(B).

#### Obligations of Covered Entity

#### Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions [provisions dependent on business arrangement]

(a) Covered Entity shall provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 CFR § 164.520, as well as any changes to such notice.

(b) Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect Business Associate's permitted or required uses and disclosures.

(c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR § 164.522.

#### Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity. [Include an exception if the Business Associate will use or disclose protected health information for, and the contract includes provisions for, data aggregation or management and administrative activities of Business Associate].

#### Term and Termination

(a) Term. The Term of this Agreement shall be effective as of [Insert Effective Date], and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section.

(b) Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall provide an opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement [and the \_\_\_\_\_ Agreement/ sections \_\_\_\_ of the \_\_\_\_\_ Agreement] if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, or immediately terminate this Agreement [and the \_\_\_\_\_ Agreement/ sections \_\_\_\_ of the \_\_\_\_\_ Agreement] if Business Associate has breached a material term of this Agreement and cure is not possible. [Bracketed language in this provision may be necessary if there is an underlying

services agreement. Also, opportunity to cure is permitted, but not required by the Privacy Rule.]

(c) Effect of Termination.

(1) Except as provided in paragraph (2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.

(2) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

Miscellaneous

(a) Regulatory References. A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.

(b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191.

(c) Survival. The respective rights and obligations of Business Associate under Section [Insert Section Number Related to AEffect of Termination≅] of this Agreement shall survive the termination of this Agreement.

(d) Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule.