

Complete Guide to HIPAA Compliance; “ Business Associates” Chapter 6. Brownstone Publishers, Inc. 2002.

HIPAAAlert @ HIPAAAdvisory.com ; Volume 3, No. 2; February 26, 2002. “ HIPAAAction: Shaping up Your Business Associates. From Phoenix Health Systems

HIPAAAlert @ HIPAAAdvisory.com ; Volume 3, No. 2; February 26, 2002. “HIPAA Law: Q/A – Writing Business Associate Contracts. From Phoenix Health Systems.

Proposed Modifications to the Standards for Privacy of Individually Identifiable Health Information; Appendix to the Preamble—Model Business Associate Contract Provisions.

HIPAAAdvisor : Q & A with Steve Fox @ HIPAAAdvisory.com : “HIPAA’s Impact on Business Associate Relationships. From Phoenix Health Systems

HIPAAAlert @ HIPAAAdvisor.com; Volume 3, No.3; March 21, 2002 HIPAA / Law Q&Q – Business Associates vs. Chain of Trust. From Phoenix Health Systems.

AHA; Regulatory Advisory ; “HIPAA Privacy Final Rule: Business Associate Agreement. March 28, 2001

BUSINESS ASSOCIATE AGREEMENT

(must be an Amendment, Addendum or Rider to another agreement for services involving the use, creation or transmission of Protected Health Information)

This Business Associate Agreement (“Agreement”), effective _____, 20____ (“Effective Date”), is entered into by and between _____ (the “Business Associate”) and _____, with an address at _____ (the “Covered Entity”) (each a “Party” and collectively the “Parties”).

The Business Associate is a _____ and the Covered Entity is a _____. The Parties have a prior _____ agreement dated _____ (the "_____ Agreement") under which the Business Associate regularly uses and/or discloses Protected Health Information in its performance of the Services described below. Both Parties are committed to complying with the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Regulation”) under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). This Agreement sets forth the terms and conditions pursuant to which Protected Health Information that is provided by, or created or received by, the Business Associate from or on behalf of the Covered Entity (“Protected Health Information”), will be handled between the Business Associate and the Covered Entity and with third parties during the term of their _____ Agreement and after its termination. The Parties agree as follows:

1. PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

1.1 Services. Pursuant to the _____ Agreement, Business Associate provides services (“Services”) for the Covered Entity that involve the use and disclosure of Protected Health Information. Except as otherwise specified herein, the Business Associate may make any and all uses of Protected Health Information necessary to perform its obligations under the _____ Agreement. All other uses not authorized by this Agreement are prohibited. Moreover, Business Associate may disclose Protected Health Information for the purposes authorized by this Agreement only, (i) to its employees, subcontractors and agents, in accordance with Section 2.1(e), (ii) as directed by the Covered Entity, or (iii) as otherwise permitted by the terms of this Agreement including, but not limited to, Section 1.2(b) below.

1.2 Business Activities of the Business Associate. Unless otherwise limited herein, the Business Associate may:

- a. use the Protected Health Information in its possession for its proper management and administration and to fulfill any present or future legal responsibilities of the Business Associate provided that such uses are permitted under state and federal confidentiality laws. **[This provision is permitted, but not required under the current regulations]**

- b. disclose the Protected Health Information in its possession to third parties for the purpose of its proper management and administration or to fulfill any present or future legal responsibilities of the Business Associate, provided that the Business Associate represents to the Covered Entity, in writing, that (i) the disclosures are required by law, as provided for in 45 C.F.R. § 164.501 or (ii) the Business Associate has received from the third party written assurances regarding its confidential handling of such Protected Health Information as required under 45 C.F.R. § 164.504(e)(4). **[This provision is permitted, but not required under the current regulations]**

1.3 Additional Activities of Business Associate. In addition to using the Protected Health Information to perform the Services set forth in Section 1.1 of this Agreement, Business Associate may:

- a. aggregate the Protected Health Information in its possession with the Protected Health Information of other covered entities that the Business Associate has in its possession through

its capacity as a business associate to said other covered entities provided that the purpose of such aggregation is to provide the Covered Entity with data analyses relating to the Health Care Operations of the Covered Entity. Under no circumstances may the Business Associate disclose Protected Health Information of one Covered Entity to another Covered Entity absent the explicit authorization of the Covered Entity. **[This provision is permitted, but not required under the current regulations]**

- b. de-identify any and all Protected Health Information provided that the de-identification conforms to the requirements of 45 C.F.R. § 164.514(b), and further provided that the Covered Entity maintains the documentation required by 45 C.F.R. § 164.514(b) which may be in the form of a written assurance from the Business Associate. Pursuant to 45 C.F.R. § 164.502(d)(2), de-identified information does not constitute Protected Health Information and is not subject to the terms of this Agreement. **[This provision is permitted, but not required under the current regulations]**

2. **RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PROTECTED HEALTH INFORMATION**

2.1 **Responsibilities of the Business Associate.** With regard to its use and/or disclosure of Protected Health Information, the Business Associate hereby agrees to do the following:

- a. use and/or disclose the Protected Health Information only as permitted or required by this Agreement or as otherwise required by law.
- b. report to the designated Privacy Officer of the Covered Entity, in writing, any use and/or disclosure of the Protected Health Information that is not permitted or required by this Agreement of which Business Associate becomes aware within ___ days of the Business Associate's discovery of such unauthorized use and/or disclosure.
- c. establish procedures for mitigating, to the greatest extent possible, any deleterious effects from any improper use and/or disclosure of Protected Health Information that the Business Associate reports to the Covered Entity. **[This provision is permitted, but not required under the current regulations]**
- d. use commercially reasonable efforts to maintain the security of the Protected Health Information and to prevent unauthorized use and/or disclosure of such Protected Health Information.
- e. require all of its subcontractors and agents that receive or use, or have access to, Protected Health Information under this Agreement to agree, in writing, to adhere to the same restrictions and conditions on the use and/or disclosure of Protected Health Information that apply to the Business Associate pursuant to section 2 of this Agreement.
- f. make available all records, books, agreements, policies and procedures relating to the use and/or disclosure of Protected Health Information to the Secretary of HHS for purposes of determining the Covered Entity's compliance with the Privacy Regulation, subject to attorney-client and other applicable legal privileges.
- g. upon prior written request, make available during normal business hours at Business Associate's offices all records, books, agreements, policies and procedures relating to the use and/or disclosure of Protected Health Information to the Covered Entity within ___ days for purposes of enabling the Covered Entity to determine the Business Associate's compliance with the terms of this Agreement.

- h. within 45 days of receiving a written request from the Covered Entity, provide to the Covered Entity such information as is requested by the Covered Entity to permit the Covered Entity to respond to a request by an individual for an accounting of the disclosures of the individual's Protected Health Information in accordance with 45 C.F.R. § 164.528.
 - i. subject to Section 5.5 below, return to the Covered Entity or destroy, within ____ days of the termination of this Agreement, the Protected Health Information in its possession and retain no copies (which for purposes of this Agreement shall mean destroy all backup tapes).
 - j. disclose to its subcontractors, agents or other third parties, and request from the Covered Entity, only the minimum Protected Health Information necessary to perform or fulfill a specific function required or permitted hereunder. **[This provision is permitted, but not required under the current regulations]**
- 2.2 Responsibilities of the Covered Entity. With regard to the use and/or disclosure of Protected Health Information by the Business Associate, the Covered Entity hereby agrees:
- a. to inform the Business Associate of any changes in the form of notice of privacy practices (the “Notice”) that the Covered Entity provides to individuals pursuant to 45 C.F.R. §164.520, and provide the Business Associate a copy of the Notice currently in use.
 - b. to inform the Business Associate of any changes in, or withdrawal of, the consent or authorization provided to the Covered Entity by individuals pursuant to 45 C.F.R. §164.506 or §164.508.
 - c. to inform the Business Associate of any opt-outs exercised by any individual from marketing and/or fundraising activities of the Covered Entity pursuant to 45 C.F.R. § 164.514(e). **[Include only if underlying agreement pertains to marketing or fundraising]**
 - d. to notify the Business Associate, in writing and in a timely manner, of any arrangements permitted or required of the Covered Entity under 45 C.F.R. part 160 and 164 that may impact in any manner the use and/or disclosure of Protected Health Information by the Business Associate under this Agreement, including, but not limited to, restrictions on use and/or disclosure of Protected Health Information as provided for in 45 C.F.R. § 164.522 agreed to by the Covered Entity.
 - e. that Business Associate may make any use and/or disclosure of Protected Health Information permitted under 45 C.F.R. § 164.512 except uses or disclosure for research are not permitted without prior approval by the covered entity.
3. **ADDITIONAL RESPONSIBILITIES OF THE PARTIES WITH RESPECT TO PROTECTED HEALTH INFORMATION** **[This section is permitted, but not required under the current regulations.]**

3.1 Responsibilities of the Business Associate with Respect to Handling of Designated Record Set. In the event that the Parties mutually agree in writing that the Protected Health Information constitutes a Designated Record Set, the Business Associate hereby agrees to do the following:

- a. at the request of, and in the time and manner designated by the Covered Entity, provide access to the Protected Health Information to the Covered Entity or the individual to whom such Protected Health Information relates or his or her authorized representative in order to meet a request by such individual under 45 C.F.R. § 164.524.
- b. at the request of, and in the time and manner designated by the Covered Entity, make any amendment(s) to the Protected Health Information that the Covered Entity directs pursuant to 45 C.F.R. § 164.526. Provided, however, that the Covered Entity makes the determination that the amendment(s) are necessary because the Protected Health Information that is the subject of the amendment(s) has been, or could foreseeably be, relied upon by the Business Associate or others to the detriment of the individual who is the subject of the Protected Health Information to be amended.

3.2 Responsibilities of the Covered Entity with Respect to the Handling of the Designated Record Set. In the event that the Parties mutually agree in writing that the Protected Health Information constitutes a Designated Record Set, the Covered Entity hereby agrees to do the following:

- a. notify the Business Associate, in writing, of any Protected Health Information that Covered Entity seeks to make available to an individual pursuant to 45 C.F.R. § 164.524 and the time, manner and form in which the Business Associate shall provide such access.
- b. notify the Business Associate, in writing, of any amendment(s) to the Protected Health Information in the possession of the Business Associate that the Business Associate shall make and inform the Business Associate of the time, form and manner in which such amendment(s) shall be made.

4. REPRESENTATIONS AND WARRANTIES [This section may not be necessary if it is included in the underlying agreement]

4.1 Mutual Representations and Warranties of the Parties.

Each Party represents and warrants to the other Party:

- a. that it is duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized or licensed, it has the full power to enter into this Agreement and to perform its obligations hereunder, and that the performance by it of its obligations under this Agreement have been duly authorized by all necessary corporate or other actions and will not violate any provision of any license, corporate charter or bylaws.
- b. that neither the execution of this Agreement, nor its performance hereunder, will directly or indirectly violate or interfere with the terms of another agreement to which it is a party, or give any governmental entity the right to suspend, terminate, or modify any of its governmental authorizations or assets required

for its performance hereunder. Each Party represents and warrants to the other Party that it will not enter into any agreement the execution and/or performance of which would violate or interfere with this Agreement.

- c. that it is not currently the subject of a voluntary or involuntary petition in bankruptcy, does not currently contemplate filing any such voluntary petition, and is not aware of any claim for the filing of an involuntary petition.
- d. that all of its employees, agents, representatives and members of its workforce, whose services may be used to fulfill obligations under this Agreement are or shall be appropriately informed of the terms of this Agreement and are under legal obligation to each Party, respectively, by contract or otherwise, sufficient to enable each Party to fully comply with all provisions of this Agreement including, without limitation, the requirement that modifications or limitations that the Covered Entity has agreed to adhere to with regards to the use and disclosure of Protected Health Information of any individual that materially affects and/or limits the uses and disclosures that are otherwise permitted under the Standard will be communicated to the Business Associate, in writing, and in a timely fashion.
- e. that it will reasonably cooperate with the other Party in the performance of the mutual obligations under this Agreement.
- f. that neither the Party, nor its shareholders, members, directors, officers, agents, employees or members of its workforce have been excluded or served a notice of exclusion or have been served with a notice of proposed exclusion, or have committed any acts which are cause for exclusion, from participation in, or had any sanctions, or civil or criminal penalties imposed under, any federal or state healthcare program, including but not limited to Medicare or Medicaid, or have been convicted, under federal or state law (including without limitation a plea of nolo contendere or participation in a first offender deterred adjudication or other arrangement whereby a judgment of conviction has been withheld), of a criminal offense related to (a) the neglect or abuse of a patient, (b) the delivery of an item or service, including the performance of management or administrative services related to the delivery of an item or service, under a federal or state healthcare program, (c) fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a healthcare item or service or with respect to any act or omission in any program operated by or financed in whole or in part by any federal, state or local government agency, (d) the unlawful, manufacture, distribution, prescription or dispensing of a controlled substance, or (e) interference with or obstruction of any investigation into any criminal offense described in (a) through (d) above. Each Party further agrees to notify the other Party immediately after the Party becomes aware that any of the foregoing representation and warranties may be inaccurate or may become incorrect. **[This provision is permitted, but not required under the current regulations]**

5. **TERMS AND TERMINATION**

5.1 **Term.** This Agreement shall become effective on the Effective Date and shall continue in effect until all obligations of the Parties have been met, unless terminated as provided in this Section 5. In addition, certain provisions and requirements of this Agreement shall survive its expiration or other termination in accordance with Section 8.3 herein.

5.2 **Termination by the Covered Entity.** As provided for under 45 C.F.R. § 164.504(e)(2)(iii), the Covered Entity may immediately terminate this Agreement and any related agreements if the Covered Entity makes the determination that the Business Associate has breached a material term of this Agreement. Alternatively, the Covered Entity may choose to: (i) provide the Business Associate with ___ days written notice of the existence of an alleged material breach; and (ii) afford the Business Associate an opportunity to cure said alleged material breach upon mutually agreeable terms. Nonetheless, in the event that mutually agreeable terms cannot be achieved within ___ days, Business Associate must cure said breach to the satisfaction of the Covered Entity within ___ days. Failure to cure in the manner set forth in this paragraph is grounds for the immediate termination of this Agreement.

5.3 **Termination by Business Associate.** If the Business Associate makes the determination that a material condition of performance has changed under the ___ Agreement or this Agreement, or that the Covered Entity has breached a material term of this Agreement, Business Associate may provide thirty (30) days notice of its intention to terminate this Agreement. Business Associate agrees, however, to cooperate with Covered Entity to find a mutually satisfactory resolution to the matter prior to terminating and further agrees that, notwithstanding this provision, it shall not terminate this Agreement so long as the ___ Agreement is in effect. **[This provision is permitted, but not required under the current regulations]**

5.4 **Automatic Termination.** This Agreement will automatically terminate without any further action of the Parties upon the termination or expiration of the ___ Agreement dated _____ between the Parties.

5.5 **Effect of Termination.** Upon the event of termination pursuant to this Section 5, Business Associate agrees to return or destroy all Protected Health Information pursuant to 45 C.F.R. § 164.504(e)(2)(I), if it is feasible to do so. Prior to doing so, the Business Associate further agrees to recover any Protected Health Information in the possession of its subcontractors or agents. If it is not feasible for the Business Associate to return or destroy said Protected Health Information, the Business Associate will notify the Covered Entity in writing. Said notification shall include: (i) a statement that the Business Associate has determined that it is infeasible to return or destroy the Protected Health Information in its possession, and (ii) the specific reasons for such determination, which reasons the Parties agree may include, but are not limited to, _____. Business Associate further agrees to extend any and all protections, limitations and restrictions contained in this Agreement to the Business Associate's use and/or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible. If it is infeasible for the Business Associate to obtain, from a subcontractor or agent any Protected Health Information in the possession of the subcontractor or agent, the Business Associate must provide a written explanation to the Covered Entity and require the subcontractors and agents to agree to extend any and all protections, limitations and restrictions contained in this Agreement to the subcontractors' and/or agents' use and/or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses and/or disclosures to the purposes that make the return or destruction of the Protected Health Information infeasible.

6. **CONFIDENTIALITY**

6.1 **Confidentiality Obligations.** In the course of performing under this Agreement, each Party may receive, be exposed to or acquire the Confidential Information including but not limited to, all information, data, reports, records, summaries, tables and studies, whether written or oral, fixed in hard copy or contained in any computer data base or computer readable form, as well as any information identified as confidential (“Confidential Information”) of the other Party. For purposes of this Agreement, “Confidential Information” shall not include Protected Health Information, the security of which is the subject of this Agreement and is provided for elsewhere. The Parties including their employees, agents or representatives (i) shall not disclose to any third party the Confidential Information of the other Party except as otherwise permitted by this Agreement, (ii) only permit use of such Confidential Information by employees, agents and representatives having a need to know in connection with performance under this Agreement, and (iii) advise each of their employees, agents, and representatives of their obligations to keep such Confidential Information confidential. Notwithstanding anything to the contrary herein, each Party shall be free to use, for its own business purposes, any ideas, suggestions, concepts, know-how or techniques contained in information received from each other that directly relates to the performance under this Agreement. This provision shall not apply to Confidential Information: (a) after it becomes publicly available through no fault of either Party; (b) which is later publicly released by either Party in writing; (c) which is lawfully obtained from third parties without restriction; or (d) which can be shown to be previously known or developed by either Party independently of the other Party.

7. **INSURANCE AND INDEMNIFICATION**

7.1 **Insurance.** [This section is permitted, but not required under the current regulations]

7.2 **Indemnification.** The Parties agree to indemnify, defend and hold harmless each other and each other’s respective employees, directors, officers, subcontractors, agents or other members of its workforce, each of the foregoing hereinafter referred to as “indemnified party,” against all actual and direct losses suffered by the indemnified party and all liability to third parties arising from or in connection with any breach of this Agreement or of any warranty hereunder or from any negligence or wrongful acts or omissions, including failure to perform its obligations under the Privacy Regulation, by the indemnifying party or its employees, directors, officers, subcontractors, agents or other members of its workforce. Accordingly, on demand, the indemnifying party shall reimburse any indemnified party for any and all actual and direct losses, liabilities, lost profits, fines, penalties, costs or expenses (including reasonable attorneys’ fees) which may for any reason be imposed upon any indemnified party by reason of any suit, claim, action, proceeding or demand by any third party which results from the indemnifying party’s breach hereunder. The Parties’ obligation to indemnify any indemnified party shall survive the expiration or termination of this Agreement for any reason. [This provision is permitted, but not required under the current regulations]

8. **MISCELLANEOUS**

8.1 **Covered Entity.** For purposes of this Agreement, Covered Entity shall include all entities covered by the joint notice of information practices (or privacy notice), which includes _____.

8.2 Business Associate. For purposes of this Agreement, Business Associate shall include the named Business Associate herein. However, in the event that the Business Associate is otherwise a covered entity under the Privacy Regulation, that entity may appropriately designate a health care component of the entity, pursuant to 45 C.F.R. § 164.504(a), as the Business Associate for purposes of this Agreement.

8.3 Survival. The respective rights and obligations of Business Associate and Covered Entity under the provisions of Sections 5.5, 7.2, 8.5, 8.8, 8.9 and Section 2.1 solely with respect to Protected Health Information Business Associate retains in accordance with Section 5.5 because it is not feasible to return or destroy such Protected Health Information, shall survive termination of this Agreement indefinitely. In addition, Section 3 shall survive termination of this Agreement, provided that the Covered Entity determines that the Protected Health Information being retained pursuant to Section 5.5 herein constitutes a Designated Record Set.

8.4 Amendments; Waiver. This Agreement may not be modified, nor shall any provision hereof be waived or amended, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

8.5 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties and the respective successors or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

8.6 Notices. Any notices to be given hereunder to a Party shall be made via U.S. Mail or express courier to such Party's address given below, and/or (other than for the delivery of fees) via facsimile to the facsimile telephone numbers listed below.

If to Business Associate, to:

Attention: _____
Fax: _____

with a copy (which shall not constitute notice) to:

Attn: _____
Fax: _____

If to Covered Entity, to:

Attention: Privacy Officer

Fax: _____

with a copy (which shall not constitute notice) to:

Attn: _____

Fax: _____

Each Party named above may change its address and that of its representative for notice by the giving of notice thereof in the manner hereinabove provided.

8.7 Counterparts; Facsimiles. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile copies hereof shall be deemed to be originals.

8.8 Disputes. If any controversy, dispute or claim arises between the Parties with respect to this Agreement, the Parties shall make good faith efforts to resolve such matters informally.

8.9 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, OR PUNITIVE DAMAGES OF ANY KIND OR NATURE, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGES.

9. DEFINITIONS.

9.1 Designated Record Set. Designated Record Set shall have the meaning set out in its definition at 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended, or revised.

9.2 Health Care Operations. Health Care Operations shall have the meaning set out in its definition at 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised.

9.3 Privacy Officer. Privacy Officer shall have the meaning as set out in its definition at 45 C.F.R. § 164.530(a)(1) as such provision is currently drafted and as it is subsequently updated, amended or revised.

9.4 Protected Health Information. Protected Health Information shall have the meaning as set out in its definition at 45 C.F.R. § 164.501, as such provision is currently drafted and as it is subsequently updated, amended or revised.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf effective as of _____, 2001.

COVERED ENTITY

BUSINESS ASSOCIATE

By: _____

By: _____

Print Name: _____

Print Name: _____

Print Title: _____

Print Title: _____

Date: _____

Date: _____

Pending a decision by HHS on the rules, the following place holder language should be considered for insertion into new or renegotiated contracts:

The parties agree to enter into a mutually acceptable amendment to this services agreement as necessary to comply with applicable federal laws and regulations governing the use and/or disclosure of individually identifiable health information. Such amendment shall be entered into on or before the date on which hospitals are required to be in compliance with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996.