

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("Agreement") is entered into by and between Insert Other Party's Name, and its affiliated covered entities ("Business Associate") and Enter CHHS Entity Name, and its affiliated covered entities ("Covered Entity"), (each a "Party" and collectively the "Parties"). This Agreement shall be effective as of the date on which the last of the Parties has executed this Agreement ("Effective Date").

RECITALS

This Agreement amends each Underlying Agreement existing as of the date hereof between the Parties and such terms shall apply to any future written or oral agreement between the parties which constitutes an Underlying Agreement, whether or not this Agreement is expressly incorporated by reference. The term "Underlying Agreement" specifically includes, but is not limited to, purchase orders issued by either Party as a Covered Entity to the other Party as a Business Associate. Capitalized terms used in this Agreement and not otherwise defined herein shall have the meanings set forth in HIPAA, which are incorporated herein by reference.

Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated there under ("HIPAA"), including but not limited to, the Standards for Privacy of Individually Identifiable Health Information, 45 Code of Federal Regulations Parts 160 and 164 ("Privacy Regulations") and implementing regulations issued by the U.S. Department of Health and Human Services and Health Information Technology for Economic and Clinical Health Act.

The parties acknowledge and agree that the Health Information Technology for Economic and Clinical Health Act and its implementing regulations as amended from time to time ("HITECH") may impose new requirements with respect to privacy, security and breach notification. The HITECH provisions applicable to business associates will be collectively referred to as the "HITECH BA Provisions." The provisions of HITECH and the HITECH BA Provisions are hereby incorporated by reference into this Agreement as if set forth in this Agreement in their entirety. Notwithstanding anything to the contrary, the HITECH BA Provisions will be effective: (I) with respect to any security breach notification provision, September 23, 2009; and (II) with respect to the other HITECH BA Provisions, February 17, 2010 or such subsequent date as may be specified in HITECH.

HIPAA establishes standards for protecting the confidentiality and security of identifiable patient health information. Pursuant to HIPAA, Covered Entity is required to enter into a business associate agreement with Business Associate to provide for the protection of the privacy of individually identifiable patient health information, and HIPAA prohibits the disclosure to or use of individually identifiable patient health information by the Business Associate if such an agreement is not in place.

The Parties acknowledge that in addition to the Underlying Agreements, the Parties have or may enter into other agreements, arrangements or understandings pursuant to which neither Party is a Business Associate of the other Party (an "Other Agreement"). This Agreement shall not be incorporated into or made a part of any Other Agreement.

1. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

- (a) Business Associate agrees to not use or disclose protected health information ("PHI") other than as permitted or required by this Agreement or as required by law.
- (b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.
- (c) Business Associate represents and warrants that it shall request from Covered Entity no more than the minimum Protected Health Information necessary to perform its services for the Covered Entity.
- (d) Business Associate will work diligently and cooperatively with Covered Entity to establish procedures and to take appropriate steps, to mitigate, to the extent reasonably possible, any harmful effects that are known to Business Associate of any Breach or unauthorized acquisition, access, use and/or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement. The Business Associate shall reasonable cooperative with Covered Entity's efforts to seek appropriate injunctive relief or

otherwise prevent or curtail such threatened or actual breach, or to recover its PHI, including complying with reasonable Corrective Action Plan.

- (e) Business Associate agrees to report to Covered Entity's Privacy Officer any use or disclosure of PHI not provided for by this Agreement of which it becomes aware, without unreasonable delay, but in no event more than five (5) business days after discovery by Business Associate. This reporting obligation shall include acquisitions, access, uses or disclosures by Business Associate, its employees, contractors, subcontractors, agents, representatives or any third party to which Business Associate disclosed Protected Health Information. Without limiting the foregoing, Business Associate shall report the acquisition, access use or disclosure even if it determines that the acquisition, access, use or disclosure does not pose a significant risk of financial, reputational or other harm to the individual who is the subject of Protected Health Information.
- (f) Prior to disclosing any Protected Health Information to any contractor, subcontractor, agent, or other representative that is authorized to receive, use, or have access to Protected Health Information under Business Associate's agreement with Covered Entity, Business Associate shall require such person to enter into written agreements with its contractors, subcontractors, agents or other representatives obligating them to adhere to the same restrictions and conditions on the use and/or disclosure of Protected Health Information that apply to Business Associate under this Agreement. If Business Associate has workforce located outside the United States, Business Associate will obtain Covered Entities written permission before disclosing PHI to those workforce members, subcontractors or agents.
- (g) Business Associate shall report to the Privacy Officer of Covered Entity any Security Incident involving Protected Health Information of which it becomes aware, without unreasonable delay, but in no event more than five (5) business days after Business Associate becomes aware of the Security Incident. Business Associate shall report the Security Incident in the following manner: (I) any actual successful Security Incident will be reported to the Covered Entity in writing without unreasonable delay, and (II) any attempted, unsuccessful Security Incident of which Business Associate becomes aware will be reported to Covered Entity orally or in writing on a reasonable basis as requested by the Covered Entity. If the HIPAA regulations are amended to remove the requirement to report unsuccessful attempts at unauthorized access, the requirement hereunder to report such unsuccessful attempts will no longer apply as of the effective date of the amendment. "Security Incident" shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with systems operations in an information system.
- (h) Business Associate will report to the Privacy Officer of Covered Entity, in writing, any Breach of Protected Health Information, without unreasonable delay, but in any event no more than one (1) business day (or any shorter period required under applicable state law) after discovery by Business Associate of such Breach. This reporting obligation shall include Breaches by Business Associate, its employees, contractors, subcontractors, agents and/or representatives. Each report of a Breach will contain all available information, including: (I) identify the nature of the non-permitted or violating use or disclosure; (II) identify the Protected Health Information used or disclosed; (III) identify who made the non-permitted or violating use or disclosure; (IV) identify who received the non-permitted or violating use or disclosure; (V) identify what corrective action the Business Associate took or will take to prevent further non-permitted or violating uses or disclosures; and (VI) identify what Business Associate did or will do to mitigate any harmful effect of the non-permitted or violating use or disclosure; and (VII) provide such other information as Covered Entity may request. In the event all information concerning a Breach cannot be obtained within the time frames described in this Section 1(h), the Business Associate shall supplement its previous report as soon as information becomes available.

Notification to individuals. At the Covered Entities option, the Business Associate will be responsible for notifying individuals of the occurrence when the Covered Entity requires notification and to pay any cost of such notifications, as well as any costs associated with the breach, including but not limited to credit monitoring. The Business Associate must obtain the Covered Entities' approval of the time, manner and content of any such notifications, provide the Covered Entity with copies of the notification, and provide the notification within sixty (60) days after discovery of the breach. The Business Associate shall have the burden of demonstrating to the Covered Entity that all notifications were made as required, including any evidence ~~demonstrating the necessity of any delay beyond the 60 day calendar notification requirement to affected individuals after the discovery of the breach by the Covered Entity or Business Associate.~~

Red Flag Rules. The Business Associate shall be responsible for implementation of the Identity Theft Monitoring Policy and Procedure to protect patient information that may be breached by the Business Associate under the Federal Trade Commission Regulations Red Flag Rules.

- (i) To the extent that Business Associate has PHI in a designated record set, Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner reasonably requested, to PHI 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 C.F.R. 164.524.
- (j) To the extent that Business Associate has PHI in a designated record set, Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 C.F.R. 164.526 at the request of Covered Entity and in the time and manner reasonably requested by Covered Entity.
- (k) Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity available to the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- (l) Business Associate agrees to document such disclosures of PHI 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 PHI in accordance with 45 C.F.R. 164.528.
- (m) Business Associate agrees to provide to Covered Entity or an Individual, in time and manner reasonably requested, information collected to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. 164.528.
- (n) If Business Associate conducts Standard Transactions for or on behalf of Covered Entity, Business Associate will comply, and will require each contractor, subcontractor, agent or representative involved with the conduct of such Standard Transactions to comply, with each applicable requirement of 45 C.F.R. Part 162. Business Associate will not enter into, or permit its contractors, subcontractors, agents or representatives to enter into any trading partner agreement in connection with the standard of Standard Transactions for or on behalf of Covered Entity that: (I) changes the definition, Health Information Condition, or use of a Health Information Element or Segment in any Standard; (II) adds any Health Information Elements or Segments to the maximum defined Health Information Set; (III) uses any code or Health Information Elements that are marked "not used" in the Standard's Implementation Specification(s) or are not in the Standard's Implementation Specification(s); or (IV) changes the meaning or intent of the Standard's Implementation Specification(s).

2. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE

- (a) Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement.
- (b) Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that such uses are permitted under state and federal confidentiality laws.
- (c) Except as otherwise limited in this Agreement, Business Associate may disclose PHI to third parties for the purpose of proper management and administration or to carry out the legal responsibilities of the Business Associate, provided that disclosures are required by law, or Business Associate obtains written 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.
- (d) Except as otherwise limited in this Agreement, Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 45 C.F.R. 164.504(e)(2)(i)(B).

3. ACCESS TO NETWORK

Business Associate agrees that while present at any Covered Entity facility and/or when accessing Covered Entity's computer network(s), it and all of its employees, agents, representatives and subcontractors shall at all times comply with any network access and other security practices, procedures and/or policies established by Covered Entity including, without limitation, those established pursuant to the HIPAA Security Rule.

4. HIPAA SECURITY RULE REQUIREMENT

Business Associate shall: (i) implement safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic PHI that it creates, receives, maintains or transmits on behalf of the Covered Entity; (ii) ensure that any agent, including a subcontractor, to whom Business Associate provides this information agrees to implement reasonable and appropriate safeguards; (iii) report to Covered Entity any security incident of which it becomes aware; and (iv) make Business Associate's policies and procedures, and documentation required by the HIPAA Security Rule relating to such safeguards, available to the Secretary of Health and Human Services for purposes of determining Covered Entity's compliance with the HIPAA Security Rule.

5. OBLIGATIONS OF COVERED ENTITY

- (a) Upon request, Covered Entity shall provide Business Associate with a copy of its notice of privacy practices.
- (b) Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule.

6. TERM AND TERMINATION

(a) Term. The Term of this Agreement shall be effective as of the date on which the last of the Parties has executed this Agreement ("Effective Date"), and shall terminate when the Underlying Agreement terminates and all of the PHI 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 PHI, 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 either:

- (1) Provide an opportunity for Business Associate to cure the breach, or end the violation and terminate this Agreement and the Underlying Agreement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
- (2) Immediately terminate this Agreement and the Underlying Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or
- (3) If neither termination nor cure are feasible, Covered Entity shall report the violation to the Secretary and take any or all other actions for remedies allowed by law or in equity.

(c) Effect of Termination.

- (1) Except as provided in paragraph (2) of this subsection, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.
- (2) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make the return or destruction infeasible. Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

7. 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.~~

- (b) **Amendment.** This Agreement shall be automatically amended to implement the requirements of any amendment to HIPAA or other applicable state or federal laws and ensure that the Parties remain in compliance with the law, effective upon the effective date of any such amendment.
- (c) **Survival.** The respective rights and obligations of Business Associate under Section 6, "Term and Termination," of this Agreement shall survive the termination of this Agreement.
- (d) **Interpretation.** Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with HIPAA.
- (e) **Contradictory Terms.** Any provision of the Underlying Agreement that is contradictory to one or more terms of this Agreement ("Contradictory Term") shall be superseded by the terms of this Agreement as of the Effective Date only to the extent it is impossible to comply with both the Contradictory Term and the terms of this Agreement.
- (f) **Response to Subpoenas.** In the event the Business Associate receives a subpoena or similar notice or request from any judicial or administrative or other party arising out of or in connection with this Agreement, including, but not limited to, any Business Associate security measures, Business Associate shall promptly forward a copy of such subpoena, notice or request to Covered Entity, and afford Covered Entity the opportunity to be part of the decision making with regard to the subpoena, including but not limited to, responding to the subpoena.
- (g) **Indemnification.** Business Associate and Covered Entity agree to indemnify, defend and hold each other harmless from and against any claim, cause of action, liability, damage, cost or expense, including attorneys' fees and court or proceeding costs arising out of or in connection with any non-permitted or violation of use or disclosure of PHI or other breach of this Agreement, as well as HIPAA, by a Party and/or any subcontractors', agents', person or representatives'.

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

INSERT OTHER PARTY'S NAME

INSERT CORRECT CHHS ENTITY

By: _____

By: _____

Print Name:

Print Name:

Title:

Title:

Date:

Date: