

BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (the “Agreement”) is effective as of [REDACTED] (“Effective Date”) by and between [REDACTED] (“Covered Entity”), and [REDACTED] (“Business Associate”).

Covered Entity and Business Associate are sometimes referred to herein individually as a “Party” and collectively, as the “Parties.”

RECITALS

WHEREAS, Covered Entity and Business Associate are parties to an agreement (the “Underlying Agreement”), pursuant to which Business Associate provides certain services to Covered Entity and, in connection with those services, Covered Entity discloses to Business Associate certain individually identifiable protected health information (“PHI” as defined below) that is subject to protection under the Health Insurance Portability and Accountability Act of 1996, as amended and supplemented from time to time (“HIPAA”) and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act; and

WHEREAS, the parties desire to comply with the HIPAA and HITECH Act standards for the privacy and security of PHI of patients of Covered Entity.

NOW THEREFORE, for and in consideration of the recitals above and the mutual covenants and conditions herein contained, Covered Entity and Business Associate enter into this Agreement to provide a full statement of their respective responsibilities.

ARTICLE 1

DEFINITIONS

1.1 **Generally**. Unless otherwise provided herein, capitalized terms shall have the same meaning as set forth in the HIPAA regulations, 45 *C.F.R.* parts 160, 162 and 164.

1.2 **Business Associate**. “Business Associate” shall mean [REDACTED].

1.3 **Breach**. “Breach” shall mean the unauthorized acquisition, access, use, or disclosure of protected health information that compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.

1.4 **Covered Entity**. “Covered Entity” shall mean [REDACTED].

1.5 **Designated Record Set**. “Designated Record Set” shall mean a group of medical records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider, (ii) The enrollment, payment, claims adjudication, and case management record systems maintained by or for a health plan; or (iii) Used in whole or part, by or for the covered entity to make decisions about individuals. For the purposes of this paragraph, the term *record* means any item, collection or grouping of information that includes protected health information and is maintained, collected, used or disseminated by or for a covered entity.

1.6 Disclosure. “Disclosure” shall mean the release, transfer, provision of, access to, or divulging in any other manner of the information outside the entity holding the information.

1.7 Electronic Protected Health Information. The term “Electronic Protected Health Information” or “ePHI” shall have the same meaning as the term Electronic Protected Health Information in 45 *C.F.R.* § 164.103.

1.8 Individual. “Individual” shall have the same meaning as the term “individual” in 45 *C.F.R.* § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 *C.F.R.* § 164.502(g).

1.9 Privacy Rule. “Privacy Rule” shall mean the privacy provisions of the Standards for Privacy and Security of Individually Identifiable Health Information at 45 *C.F.R.* part 160 and part 164, subparts A and E.

1.10 Protected Health Information. The term “Protected Health Information” or “PHI” shall have the same meaning as the term “protected health information” in 45 *C.F.R.* § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

1.11 Required By Law. “Required By Law” shall have the same meaning as the term “required by law” in 45 *C.F.R.* § 164.103.

1.12 Secretary. “Secretary” shall mean the Secretary of the Department of Health and Human Services, or his/her designee.

1.13 Security Incident. “Security Incident” shall have the meaning as the term “Security Incident” in 45 *C.F.R.* § 164.304.

1.14 Standards for Privacy and Security. “Standards for Privacy and Security” shall mean the provisions of the Standards for Privacy and Security of Individually Identifiable Health Information at 45 *C.F.R.* part 160 and part 164, subparts A and E.

1.15 Underlying Agreement. Pursuant to the Agreement between the Parties executed on or about [REDACTED], Business Associate provides services (the “Services”) to the Covered Entity that involve the use and disclosure of PHI. Business Associate agrees to use and disclose PHI only as authorized by this Agreement.

1.16 Use. With respect to individually identifiable health information, “Use” shall mean the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

ARTICLE 2

SCOPE OF USE OF PHI

2.1 Performance of Agreement. Business Associate, its employees, agents and independent contractors (collectively referred to as “Business Associate”) may use PHI solely (1) to perform its duties under the Underlying Agreement, (2) as directed by the Covered Entity, and (3) as allowed by the terms of the Underlying Agreement and this Agreement. All other uses or disclosures not authorized by this Agreement are prohibited.

2.2 Safeguards for Protection of PHI. Business Associate agrees that it will:

(a) use commercially reasonable efforts to protect and safeguard from any oral and written disclosure all PHI, regardless of the type of media on which it is stored (e.g., written or electronic, etc.), with which it may come into contact in accordance with applicable statutes and regulations, including, but not limited to, HIPAA and the HITECH Act;

(b) implement and maintain administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of the PHI and ePHI that Business Associate creates, receives, maintains or transmits; and

(c) use appropriate safeguards to prevent use or disclosure of PHI and ePHI other than as permitted by this Agreement or required by law.

2.3 Reporting of Unauthorized Use. Business Associate shall promptly report to Covered Entity in writing within fifteen (15) days of discovery of any unauthorized acquisition, access, use or disclosure of PHI in violation of this Agreement or any law, or any Security Incident (“the Breach”). Such written notice to Covered Entity shall include the identity of each individual whose PHI was, or was reasonably believed to have been, breached; a brief description of what happened, including the date of the Breach and date of discovery of the Breach; a description of the PHI that was involved in the Breach; any steps the individual(s) should take to protect themselves from potential harm from the Breach; a description of what Business Associate is doing to investigate the breach, mitigate harm to the individual(s) and protect against further Breaches; and contact procedures for individual(s) to ask questions or get additional information. Business Associate shall implement and maintain sanctions against any employee, subcontractor, or agent who violates the requirements of this Agreement or the HIPAA regulations. Business Associate shall, as requested by Covered Entity, take steps to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement.

2.4 Use of Subcontractors. To the extent Business Associate uses one or more subcontractors or agents to provide services under the Underlying Agreement, and such subcontractors or agents receive or have access to PHI, Business Associate agrees that it will ensure that each such subcontractor or agent shall agree to all of the same restrictions, terms and conditions that apply to Business Associate in this Agreement, including but not limited to implementation of reasonable and appropriate safeguards to protect ePHI.

2.5 Breach or Misuse of PHI. Business Associate recognizes that any breach of confidentiality or misuse of information found in and obtained from records may result in the

termination of the Underlying Agreement.

ARTICLE 3

AVAILABILITY, AMENDMENT OF PHI

3.1 Availability of PHI. If Business Associate maintains a Designated Record Set, Business Associate agrees to provide access, at the request of Covered Entity, and in the time and manner designated by Covered Entity, to PHI in the Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements of 45 C.F.R. §164.524.

3.2 Amendments to PHI. If Business Associate maintains a Designated Record Set, Business Associate agrees to make any amendment(s) to the 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 or an Individual, and in the time and manner designated by Covered Entity.

ARTICLE 4

ACCOUNTING AND INSPECTIONS

4.1 Accounting of Disclosures. 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.

4.2 Provide Accounting. 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 4.1 of this Agreement, 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.

4.3 Access by DHHS. Business Associate shall make its internal practices, books and records relating to the use and disclosure of PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity available to the Secretary of the Department of Health and Human Services or designee (“DHHS”) for purposes of determining Covered Entity’s compliance with HIPAA, the HITECH Act and the corresponding privacy and security regulations. Upon Covered Entity’s request, Business Associate shall provide Covered Entity with copies of any information it has made available to DHHS under this section of the Agreement.

ARTICLE 5

OBLIGATIONS OF COVERED ENTITY

5.1 Notice of Privacy Practices. Covered Entity shall provide Business Associate with the notice of privacy practices that Covered Entity produces in accordance with 45 *C.F.R.* §164.520, as well as any changes to such notice.

5.2 Changes in Use of PHI. Covered Entity shall provide Business Associate with any changes in, or revocation of, permission by Individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures.

5.3 Restrictions on Use of PHI. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 *C.F.R.* § 164.522.

ARTICLE 6

TERM/TERMINATION

6.1 Term and Termination. This Agreement shall terminate when all of the PHI and ePHI 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 not feasible to return or destroy the PHI or e-PHI, protections are to extend to such information, in accordance with the provisions of this Agreement.

6.2 Termination After Notice and Right to Cure. If the Covered Entity reasonably determines that the Business Associate has committed a material breach of this Agreement, Business Associate shall have thirty (30) calendar days, after delivery from Covered Entity of written notice pursuant to Section 8.2, to remedy the breach and provide evidence of cure to the Covered Entity. If such material breach is not cured within that time, Covered Entity may terminate this Agreement or the Underlying Agreement without additional notice to Business Associate. For the purposes of this Agreement, material breach shall include, but not be limited to, improper use or disclosure of PHI or failure to implement protective safeguards or diminution of Business Associates' reported security procedures which are satisfactory to the Covered Entity, as determined by the Covered Entity in its sole discretion.

6.3 Termination After Repeated Material Breaches. Covered Entity may terminate this Agreement and the Underlying Agreement without penalty if Business Associate commits repeated material breaches of this Agreement or any provision hereof, irrespective of whether, or how promptly, Business Associate may remedy such violation after being notified of the same. Repeated material breach means more than one material breach of this Agreement.

6.4 Return and Destruction of PHI. Within fifteen (15) business days of the expiration or earlier termination of this Agreement or Underlying Agreement for whatever reason, Business Associate agrees that it will return or destroy all PHI, if feasible, received from, or created or received by it on behalf of Covered Entity, that Business Associate maintains in any form, and retain no copies of such information.

6.5 No Feasible Return and Destruction of PHI. To the extent such return or destruction of PHI is not feasible, Business Associate shall extend the precautions of this Agreement to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information unfeasible. Business Associate shall remain bound by the provisions of this Agreement, even after termination of this Agreement or the Underlying Agreement until such time as all PHI has been returned or otherwise destroyed as provided in this section.

6.6 Effect of Termination. All rights, duties and obligations of Business Associate established in this Agreement shall survive the termination of this Agreement.

ARTICLE 7

INDEMNIFICATION

7.1 Business Associate agrees to defend, indemnify, save, and hold Covered Entity and its employees, officers, and directors harmless from and against any and all liability, loss, damages, claims, actions, judgments, costs, fines, penalties or expenses, including, but not limited to, any award, settlement, or reasonable attorney's fees and costs, which arise out of acts or omissions to act by Business Associate or its employees, contractors or agents in connection with the performance of its duties and responsibilities pursuant to the terms of this Agreement.

7.2 In the event of the receipt by Business Associate of a written notice of claim or cause of action which is covered under the indemnification provisions contained in this Article 7, Business Associate shall promptly advise the Covered Entity in writing of the claim, but in any event in time for Covered Entity to file a responsive pleading if a lawsuit has been commenced.

7.3 Notwithstanding anything contained in this Agreement to the contrary, Business Associate's obligations under this Article 7 shall survive the termination of this Agreement.

ARTICLE 8

OTHER PROVISIONS

8.1 Construction. This Agreement shall be construed as broadly as necessary to implement and comply with HIPAA and the HITECH Act and the regulations promulgated thereunder. The parties agree that any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Standards for Privacy and Security, HIPAA, the HITECH Act and any amendments thereto.

8.2 Notice. All notices and other communications required or permitted pursuant to this Agreement shall be in writing, addressed to the party at the address set forth at the end of this Agreement, or to such other address as either party may designate from time to time. All notices and other communications shall be mailed by registered or certified mail, return receipt requested, postage pre-paid, or transmitted by hand delivery or telegram. All notices shall be effective as of the date of delivery of personal notice or on the date of receipt, whichever is applicable.

8.3 Amendments. The parties recognize that this Agreement may need to be modified from time to time to ensure consistency with amendments to and changes in applicable federal and state laws and regulations, including, but not limited to, HIPAA and the HITECH Act. This Agreement constitutes the entire agreement between the parties with respect to its subject matter. No oral statement or prior written material not specifically mentioned herein shall be of any force or effect and no change in or addition to this Agreement shall be recognized unless evidenced by a writing executed by Covered Entity and Business Associate, such amendment(s) to become effective on the date stipulated therein. 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 Standards for Privacy and Security, HIPAA, the HITECH Act and any amendments thereto.

8.4 Assignment. Covered Entity has entered into this Agreement in specific reliance on the expertise and qualifications of Business Associate. Consequently, Business Associate's interest under this Agreement may not be transferred or assigned or assumed by any other person, in whole or in part, without the prior written consent of Covered Entity.

8.5 Governing Law. This Agreement has been executed and delivered in, and shall be interpreted, construed, and enforced pursuant to and in accordance with, the laws of the Commonwealth of Pennsylvania.

8.6 Headings. Headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

8.7 Binding Effect. This Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective permitted successors and assigns.

8.8 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall constitute an original and all of which shall constitute but one Agreement.

8.9 Gender and Number. The use of the masculine, feminine or neuter genders, and the use of the singular and plural, shall not be given an effect of any exclusion or limitation herein. The use of the word "person" or "party" shall mean and include any individual, trust, corporation, partnership or other entity.

8.10 Priority of Agreement. If any portion of this Agreement is inconsistent with the terms of the Underlying Agreement, the terms of this Agreement shall prevail. Except as set forth above, the remaining provisions of the Underlying Agreement are to be ratified in their entirety.

8.11 No Construction Against Drafter. This Agreement is not to be construed against the drafting party.

8.12 Authority To Contract. Each party represents and warrants that said party is authorized to enter into this Agreement and to be bound by the terms of it.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have hereunto set their hands effective the day and year first above written.

FOR COVERED ENTITY:

FOR BUSINESS ASSOCIATE:

Name:

Name:

By: _____

By: _____