

## BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (“Agreement”) by and between \_\_\_\_\_, hereinafter referred to as “Covered Entity,” and \_\_\_\_\_, hereinafter referred to as “Business Associate,” each (individually referred to as a “Party” and collectively as the “Parties”) is made effective this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_ (the “Effective Date”).

### RECITALS:

WHEREAS, the Parties wish to enter into or have entered into an arrangement whereby Business Associate will provide certain services for or on behalf of Covered Entity, and pursuant to such arrangement, Business Associate may be considered a “business associate,” as that term is defined in the Health Insurance Portability and Accountability Act of 1996, (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and regulations promulgated thereunder by the U.S. Department of Health and Human Services (“DHHS”), as amended from time to time (the “HIPAA Regulations”), and other applicable laws. The agreement evidencing such arrangement is reflected in a written agreement dated \_\_\_\_\_ (hereinafter referred to “Arrangement Agreement”). This Agreement is hereby incorporated into and made a part of the Arrangement Agreement;

WHEREAS, Business Associate will have access to individually identifiable health information (hereinafter, “Protected Health Information” or “PHI”), as that term is defined in 45 CFR §160.103, in connection with the performance of services pursuant to the Arrangement Agreement; and

WHEREAS, the Parties intend that this Agreement will govern the terms and conditions under which PHI may be used or disclosed by Business Associate in conformity with the Standards for Privacy of Individually Identifiable Health Information set forth in 45 CFR, Parts 160 and 164 (the “Privacy Regulations”) and the Security Standards for the Protection of Electronic Protected Health Information set forth at 45 CFR, Parts 160 and 164 (the “Security Regulations”) (hereinafter collectively referred to as the “Privacy and Security Regulations”), promulgated under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

NOW, THEREFORE, in consideration of the Parties' continuing obligations under the Arrangement Agreement, compliance with the Privacy and Security Regulations, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows.

The above recitals are true and correct and are hereby made a substantive part of this Agreement.

### **I. DEFINITIONS**

(A). Except as otherwise defined herein, any and all terms in this Agreement shall have the definitions set forth in HIPAA, HITECH and the HIPAA Regulations..

(B). For purposes of this Agreement, “Protected Health Information” or “PHI” shall have the meaning given to such term under HIPAA, and shall mean individually identifiable health information maintained or transmitted in any form of medium, including, without limitation, all

information (including demographic, medical, and financial information), data, documentation, and materials that relate to (i) the past, present and future physical or mental health or condition of an individual; (ii) the provision of health care to an individual for purposes of both treatment and research; (iii) the past, present, or future payment for the provision of health care to an individual. PHI does not include health information that has been de-identified in accordance with the standards for de-identification provided for in the HIPAA Privacy Regulations.

## **II. COMPLIANCE WITH LAW**

Business Associate shall carry out its obligations under this Agreement so as to (i) ensure that the provision of services contemplated under the Arrangement Agreement complies with all applicable laws and regulations, including without limitation the Privacy and Security Regulations, to protect the privacy and security of any PHI that is accessed as a result of the services provided pursuant to the Arrangement Agreement, and (ii) implement any changes required during the term of this Agreement which are necessary to adapt the services to comply with any future applicable laws or regulations, including, with limitation, additional privacy and security requirements promulgated under HIPAA, HITECH, the HIPAA Regulations and other applicable State and Federal laws and regulations.

## **III. COORDINATION WITH HIPAA PRIVACY/SECURITY RULE**

In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the Privacy and Security Regulations, as amended, the Privacy and Security Regulations in effect at the time shall control. Where provisions of this Agreement are different than those mandated in the Privacy and Security Regulations, but are nonetheless permitted by the Privacy and Security Regulations, the provisions of this Agreement shall control.

The Parties agree that, in the event that any documentation of the arrangement pursuant to which Business Associate provides services for or on behalf of Covered Entity contains provisions relating to the use or disclosure of PHI, which are more restrictive than the provisions of this Agreement, the provisions of the more restrictive documentation will control. The provisions of this Agreement are intended to establish the minimum requirements regarding Business Associate's use and disclosure of PHI.

## **IV. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE**

(A). Scope. Business Associate acknowledges and agrees that all PHI that is created or received by Covered Entity and disclosed or made available in any form, including but not limited to paper record, oral communication, audio recording and electronic display by Covered Entity to Business Associate or is created or received by Business Associate for or on behalf of Covered Entity shall be subject to this Agreement.

(B). Prohibited Uses and Disclosures. Business Associate agrees not to use or further disclose PHI obtained or accessible by it as a result of its performance under the Arrangement Agreement other than as permitted or required by this Agreement or as required by law.

(C). Security Standards. Business Associate will implement and maintain security safeguards to ensure that PHI obtained by or on behalf of Covered Entity is not used or disclosed by Business Associate in violation of this Agreement. Business Associate will implement administrative, physical, and technical 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, in the same manner as it would if the Business Associate were a Covered Entity. Business Associate acknowledges that HITECH requires Business Associate to comply with 45 C.F.R. section 164.308, 164.310, 164.312, and 164.316, as if the Business Associate were a Covered Entity.

(D). Reporting and Mitigating the Effect of Unauthorized Uses and Disclosures. If Business Associate has knowledge of any use or disclosure of PHI not provided for by this Agreement, Business Associate will notify Covered Entity in accordance with Section VIII(I). Business Associate will establish and implement procedures and other reasonable efforts for mitigating harmful effects arising from improper use and/or disclosure of PHI. .

(E). HIPAA Data Breach Notification and Mitigation. Business Associate agrees to implement a reasonable system for the discovery and prompt reporting of any “breach” of “unsecured PHI,” as those terms are defined in 45 C.F.R. section 164.402. The Parties acknowledge and agree that 45 C.F.R. section 164.404 *et seq.* govern when a breach shall be treated as discovered, the timeline by which Business Associate must provide notice of a breach, and the information that must be provided in such notice. Business Associate agrees to be responsible for any and all costs associated with such notification and mitigation of a breach of unsecured PHI. The Parties further acknowledge that Business Associate is not acting as the agent of Covered Entity under the Arrangement Agreement.

(F). Reporting Security Incidents. Business Associate agrees it will promptly report to Covered Entity any “security incident” of which it becomes aware, as this term is defined in the HIPAA Security Regulations.

(G). Subcontractors. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides or who has access to PHI agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information, including implementing reasonable and appropriate safeguards to protect such information.

(H). Access. Business Associate agrees to promptly make PHI available to an individual who has a right of access to inspect and obtain a copy of the PHI about the individual, to the extent and in the manner required by the Privacy Rule, 45 CFR §164.524. Business Associate shall promptly provide notice to Covered Entity of a request made to Business Associate for access to PHI by an individual.

(I). Amendment. Business Associate agrees to promptly make PHI available for amendment and incorporate any amendments to PHI made or authorized by Covered Entity in accordance with the requirements of the Privacy Rule, 45 CFR §164.526. Business Associate shall promptly provide notice to Covered Entity of a request made to Business Associate for any amendments to PHI by an individual.

(J). Accounting. Business Associate agrees to document any disclosures of PHI as would be required for Covered Entity to respond to a request by and Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. section 164.528, as amended by HITECH). Business Associate agrees to provide to Covered Entity such information collected in order 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. section 164.528, as amended by HITECH

(K). Audit, Inspection and Enforcement by Covered Entity. With reasonable notice and during regular business hours, Covered Entity may audit Business Associate to monitor compliance with this Agreement. Business Associate will correct any violation of this Agreement found by Covered Entity and will certify in writing that the correction has been made. Business Associate will make its internal practices, books, records, policies, and procedures relating to the use and disclosure of PHI received from, or created or received by Business associate on behalf of Covered Entity, available to HHS, or its agents for purposes of monitoring Covered Entity's or Business Associate's compliance with the Privacy and Security Rules, and HITECH.

(L). Books and Records. 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 for or on behalf of Covered Entity available to Covered Entity, or at the request of Covered Entity to the Secretary of Health and Human Services (the "Secretary") for purposes of determining the Covered Entity's compliance with the HIPAA Regulations. In responding to any such request that Business Associate make its internal practices, book and records available to the Secretary, Business Associate shall not initially furnish documents or information protected from disclosure by ethical obligations of confidentiality and/or any other applicable privilege or ethical obligation unless Covered Entity expressly authorized Business Associate to do so.

## **V. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE**

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, provided that such use or disclosure would not violate the Security and Privacy Regulations if done by Covered Entity. Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate. To the extent Business Associate discloses PHI to a third party, Business Associate must obtain, prior to making such disclosure: (i) reasonable assurances from such third party that such PHI will be held confidential as provided pursuant to this Agreement, and only disclosed as required by law or for the purposes for which it was disclosed to such third party, and (ii) an agreement from such third party to immediately notify Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

## **VI. TERM AND TERMINATION**

(A). Term. The Term of this Agreement shall be effective on the Effective Date, and shall remain in effect for the duration of all services Business Associate provides to Covered Entity, unless sooner terminated under this Agreement, and for so long as Business Associate shall remain in possession of any PHI received from, or created or received by Business Associate on behalf of Covered Entity.

(B). Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate or Business Associate's refusal to implement any changes that are required or reasonably requested to ensure Covered Entity's compliance with any future applicable laws or regulations, including, with limitation, additional privacy and security requirements promulgated under HIPAA and other applicable State and Federal laws and regulations, Covered Entity shall have the right to immediately terminate this Agreement and the Arrangement Agreement with written notice to Business Associate.

(C). Effect of Termination.

i. Except as provided in paragraph (ii) of this subsection, upon termination of this Agreement, the Arrangement Agreement or upon request of Covered Entity, whichever occurs first, Business Associate shall return or destroy all PHI received from or on behalf of 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.

ii. 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 return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of PHI is 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. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. This provision shall survive any termination or expiration of this Agreement.

iii. The obligations of Business Associate under this Section VI(C) shall survive the expiration, termination, or cancellation of this Agreement, the Arrangement Agreement and/or the business relationship of the parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein.

**VII. INDEMNIFICATION**

Business Associate shall indemnify and hold Covered Entity, its affiliates, directors, officers, employees and agents, harmless from and against all claims, actions, causes of action, demands, liabilities, judgments, fines, assessments, penalties, awards, or other expenses, of any kind or nature whatsoever, including, without limitation, attorney's fees and costs, relating to or arising out of any breach or alleged breach of this Agreement or any provision of the Privacy and Security Regulations by Business Associate.

**VIII. MISCELLANEOUS**

(A). No Rights in Third Parties. Except as expressly stated herein or the Privacy or Security Regulations, the Parties to this Agreement do not intend to create any rights in any third parties.

(B). Amendment. This Agreement may be amended or modified only in a writing signed by the Parties. Notwithstanding the foregoing, the Parties agree that this Agreement will be automatically amended to conform to any future applicable laws or regulations, including, with limitation, additional privacy and security requirements promulgated under HIPAA, HITECH and other applicable State and Federal laws and regulations.

(C). Assignment. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party.

(D). Independent Contractor. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effectuating the provisions of this Agreement and any other agreements between the Parties evidencing their

business relationship.

(E). Governing Law. This Agreement will be governed by the laws of the State of New Jersey without regard to its conflict of laws principles.

(F). No Waiver. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

(G). Interpretation. The terms of this Agreement shall be construed in light of the official interpretation and/or guidance on HIPAA, the Privacy Regulation and/or the Security Regulation issued by HHS, the Office of Civil Rights or the Centers for Medicare and Medicaid Services from time to time.

(H). Severability. In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect.

(I). Notice. Any notification required in this Agreement shall be made in writing to the representative of the other Party who signed this Agreement or the person currently serving in that representative's position with the other Party.

(J). Counterpart and Electronic Execution. This Agreement may be executed in any number of counterparts with the same effect as if all the Parties had signed the same document. Such executions may be transmitted to the Parties electronically or by facsimile and such electronic or facsimile execution shall have the full force and effect of an original signature. All fully executed counterparts, whether original, electronic or facsimile executions or a combination, shall be construed together and constitute on and the same agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written above.

COVERED ENTITY:

BUSINESS ASSOCIATE:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Print Name

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Title

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Title