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HIPAA BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (“BAA”) is entered into this ____ day of _____, 20____ (“Effective Date”), by and between [Vendor Name] (“Business Associate”), and the State of Delaware, Department of [Agency/Division Name] (“Covered Entity”) (collectively, the “Parties”).

RECITALS

WHEREAS, The Parties have entered, and may in the future enter, into one or more arrangements or agreements (the “Agreement”) which require the Business Associate to perform functions or activities on behalf of, or services for, Covered Entity or a Covered Entity Affiliate (“CE Affiliate”) that involve the use or disclosure of either (a) Protected Health Information (“PHI”) that is subject to the final federal Privacy, Security, Breach Notification and Enforcement Rules (collectively the “HIPAA Rules”) issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (the Act including the HIPAA rules shall be referred to as “HIPAA”) and the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), or (b) health information relating to substance abuse and treatment (“Part 2 PHI”) protected under the Federal Confidentiality of Alcohol and Drug Abuse Patient Records law and regulations, 42 USC §290dd-2 and 42 CFR Part 2 (collectively, “Part 2”), as each is amended from time to time. The purpose of this BAA is to set forth the obligations of the Parties with respect to such PHI and Part 2 PHI.

WHEREAS, Business Associate provides [professional services] for Covered Entity pursuant to a contract dated _____, 201[] and such other engagements as shall be entered into between the parties in the future in which Covered Entity discloses certain PHI or Part 2 PHI to Business Associate (collectively, the “Master Agreement”);

WHEREAS, Business Associate, in the course of providing services to Covered Entity, may have access to PHI and may be deemed a business associate for certain purposes under HIPAA;

WHEREAS, Business Associate is also a Qualified Service Organization (“QSO”) under Part 2 and must agree to certain mandatory provisions regarding the use and disclosure Part 2 PHI;

WHEREAS, the Parties contemplate that Business Associate may obtain PHI, with Covered Entity’s knowledge and consent, from certain other business associates of Covered Entity that may possess such PHI; and

WHEREAS, Business Associate and Covered Entity are entering into this BAA to set forth Business Associate’s obligations with respect to its handling of the PHI, whether such PHI was obtained from another business associate of Covered Entity or directly from Covered Entity;

NOW, THEREFORE, for mutual consideration, the sufficiency and delivery of which is acknowledged by the Parties, and upon the premises and covenants set forth herein, the Parties agree as follows:

1. **Definitions.** Unless otherwise defined herein, capitalized terms used in this BAA shall have the meanings ascribed to them in HIPAA or the Master Agreement between Covered Entity and Business Associate, as applicable.

2. **Obligations and Activities of Business Associate.** To the extent that Business Associate is provided with or creates any PHI on behalf of Covered Entity and is acting as a business associate of Covered Entity, Business Associate agrees to comply with the provisions of HIPAA applicable to business associates, and in doing so, represents and warrants as follows:

(a) **Use or Disclosure.** Business Associate agrees to not use or disclose PHI other than as set forth in this BAA, the Master Agreement, or as required by law.

(b) **Specific Use of Disclosure.** Except as otherwise limited by this BAA, Business Associate may:

(i) use or disclose PHI to perform data aggregation and other services required under the Master Agreement to assist Covered Entity in its operations, as long as such use or disclosure would not violate HIPAA if done by Covered Entity, or HIPAA permits such use or disclosure by a business associate;

(ii) use or disclose PHI for the proper management and administration of Business Associate or to carry out Business Associate's legal responsibilities, provided that with respect to disclosure of PHI, such disclosure is required by law, or 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 the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached; and

(iii) de-identify PHI and maintain such de-identified PHI indefinitely, notwithstanding Section 4 of this Agreement, provided that all identifiers are destroyed or returned in accordance with the Privacy Rule.

(c) **Minimum Necessary.** Business Associate agrees to take reasonable efforts to limit requests for, or uses and disclosures of, PHI to the extent practical, a limited data set, otherwise to the minimum necessary to accomplish the intended request, use, or disclosure.

(d) **Safeguards.** Business Associate shall establish appropriate safeguards, consistent with HIPAA, that are reasonable and necessary to prevent any use or disclosure of PHI not expressly authorized by this BAA.

(i) To the extent that Business Associate creates, receives, maintains, or transmits Electronic PHI, Business Associate agrees to establish 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 Covered Entity, as required by the Privacy Rule and Security Rule.

(ii) The safeguards established by Business Associate shall include securing PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity in accordance with the standards set forth in HITECH Act §13402(h) and any guidance issued thereunder.

(iii) Business Associate agrees to provide Covered Entity with such written documentation concerning safeguards as Covered Entity may reasonably request from time to time.

(e) **Agents and Subcontractors.** Business Associate agrees to obtain written assurances that any agents, including subcontractors, to whom it provides PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, agree to the same restrictions and conditions that apply to Business Associate with respect to such PHI, including the requirement that it agree to implement reasonable and appropriate safeguards to protect Electronic PHI that is disclosed to it by Business Associate. To the extent permitted by law, Business Associate shall be fully liable to Covered Entity for any and all acts, failures, or omissions of Business Associate's agents and subcontractors in any breach of their subcontracts or assurances to Business Associate as though they were Business Associate's own acts, failures, or omissions.

(f) **Reporting.** Within five (5) business days of discovery by Business Associate, Business Associate agrees to notify Covered Entity in writing of any use or disclosure of, or Security Incident involving, PHI, including any Breach of Unsecured PHI, not provided for by this BAA or the Master Agreement, of which Business Associate may become aware.

(i) In the notice provided to Covered Entity by Business Associate regarding unauthorized uses and/or disclosures of PHI, Business Associate shall describe the remedial or proposed mitigation efforts required under Section 2(g) of this BAA.

(ii) Specifically with respect to reporting a Breach of Unsecured PHI, Business Associate agrees to must include the identity of the individual(s) whose Unsecured PHI was Breached in the written notice provided to Covered Entity, and any additional information required by HIPAA.

(ii) Business Associate agrees to cooperate with Covered Entity upon report of any such Breach so that Covered Entity may provide the individual(s) affected by such Breach with proper notice as required by HIPAA.

(g) **Mitigation.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate resulting from a use or disclosure of PHI by Business Associate in violation of the requirements of this BAA or the Master Agreement.

(h) **Audits and Inspections.** Business Associate agrees to make its internal practices, books, and records, including policies and procedures, relating to the use and disclosure of PHI available to the Secretary, in a time and manner mutually agreed to by the Parties or designated by the Secretary, for purposes of the Secretary determining the Covered Entity's compliance with HIPAA.

(i) **Accounting.** Business Associate agrees to document and report to Covered Entity, within fourteen (14) days, Business Associate's disclosures of PHI so Covered Entity can comply with its accounting of disclosure obligations in accordance with 45 C.F.R. §164.528 and any subsequent regulations issued thereunder. Business Associate agrees to

maintain electronic records of all such disclosures for a minimum of six (6) calendar years.

(j) **Designated Record Set.** While the Parties do not intend for Business Associate to maintain any PHI in a designated record set, to the extent that Business Associate does maintain any PHI in a designated record set, Business Associate agrees to make available to Covered Entity PHI within fourteen (14) days:

(i) for Covered Entity to comply with its access obligations in accordance with 45 C.F.R. §164.524 and any subsequent regulations issued thereunder; and

(ii) for amendment upon Covered Entity's request and incorporate any amendments to PHI as may be required for Covered Entity comply with its amendment obligations in accordance with 45 C.F.R. §164.526 and any subsequent guidance.

(k) **HITECH Compliance Dates.** Business Associate agrees to comply with the HITECH Act provisions expressly addressed, or incorporated by reference, in this BAA as of the effective dates of applicability and enforcement established by the HITECH Act and any subsequent regulations issued thereunder.

(l) **Part 2 QSO Compliance.**

(i) To the extent that in performing its services for or on behalf of Covered Entity, Business Associate uses, discloses, maintains, or transmits Part 2 PHI, Business Associate acknowledges and agrees that it is a QSO for the purpose of such federal law; acknowledges and agrees that in receiving, storing, processing or otherwise dealing with any such patient records, it is fully bound by the Part 2 regulations; and, if necessary will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the Part 2 regulations.

(ii) Notwithstanding any other language in this Agreement, Business Associate acknowledges and agrees that any patient information it receives from Covered Entity that is protected by Part 2 is subject to protections that may prohibit Business Associate from disclosing such information to agents or subcontractors without the specific written consent of the subject individual.

(iii) Business Associate acknowledges that any unauthorized disclosure of information under this section is a federal criminal offense.

3. Obligations of Covered Entity.

(a) Covered Entity agrees to notify Business Associate of any limitation(s) in Covered Entity's notice of privacy practices in accordance with 45 C.F.R. §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.

(b) Covered Entity agrees to notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose PHI, including disclosure of data to insurers and health plans when the patient pays for medical services in full and requests that such notification not be made, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

(c) Covered Entity agrees to 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, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

(d) Covered Entity agrees to limit its use, disclosure, and requests of PHI under this BAA to a limited data set or, if needed by Covered Entity, to the minimum necessary PHI to accomplish the intended purpose of such use, disclosure, or request.

4. **Term and Termination.**

(a) **Term.** This BAA shall become effective upon the Effective Date and, unless otherwise terminated as provided herein, shall have a term that shall run concurrently with that of the last expiration date or termination of the Master Agreement.

(b) **Termination Upon Breach.** Without limiting the termination rights of the Parties pursuant to the Master Agreement, upon either Party's knowledge of a material breach by the other Party to this BAA, the breaching Party shall notify the non-breaching Party of such breach and the breaching party shall have fourteen (14) days from the date of notification to the non-breaching party to cure such breach. In the event that such breach is not cured, or cure is infeasible, the non-breaching party shall have the right to immediately terminate this BAA and those portions of the Master Agreement that involve the disclosure to Business Associate of PHI, or, if nonseverable, the Master Agreement.

(c) **Termination by Either Party.** Either Party may terminate this BAA upon provision of thirty (30) days' prior written notice.

(d) **Effect of Termination.**

(i) To the extent feasible, upon termination of this BAA or the Master Agreement for any reason, Business Associate agrees, and shall cause any subcontractors or agents to return or destroy and retain no copies of all PHI received from, or created or received by Business Associate on behalf of, Covered Entity. Business Associate agrees to complete such return or destruction as promptly as possible and verify in writing within thirty (30) days of the termination of this BAA to Covered Entity that such return or destruction has been completed.

(ii) If not feasible, Business Associate agrees to provide Covered Entity notification of the conditions that make return or destruction of PHI not feasible. Upon notice to Covered Entity that return or destruction of PHI is not feasible, Business Associate agrees to extend the protections of this BAA to such PHI for as long as Business Associate maintains such PHI.

(iii) Without limiting the foregoing, Business Associate may retain copies of PHI in its workpapers related to the services provided in the Master Agreement to meet its professional obligations.

5. **Miscellaneous.**

(a) **Regulatory References.** A reference in this BAA to a section in the Privacy Rule or Security Rule means the section as in effect or as amended.

(b) **Amendment.** The Parties acknowledge that the provisions of this BAA are designed to comply with HIPAA and agree to take such action as is necessary to amend this BAA from time to time as is necessary for Covered Entity to comply with the requirements of

HIPAA. Regardless of the execution of a formal amendment of this BAA, the BAA shall be deemed amended to permit the Covered Entity and Business Associate to comply with HIPAA.

(c) **Method of Providing Notice.** Any notice required to be given pursuant to the terms and provisions of this BAA shall be in writing and may be either personally delivered or sent by registered or certified mail in the United States Postal Service, Return Receipt Requested, postage prepaid, addressed to each Party at the addresses listed in the Master Agreement currently in effect between Covered Entity and Business Associate. Any such notice shall be deemed to have been given if mailed as provided herein, as of the date mailed.

(d) **Parties Bound.** This BAA shall inure to the benefit of and be binding upon the Parties hereto and their respective legal representatives, successors, and assigns. Business Associate may not assign or subcontract the rights or obligations under this BAA without the express written consent of Covered Entity. Covered Entity may assign its rights and obligations under this BAA to any successor or affiliated entity.

(e) **No Waiver.** No provision of this BAA or any breach thereof shall be deemed waived unless such waiver is in writing and signed by the Party claimed to have waived such provision or breach. No waiver of a breach shall constitute a waiver of or excuse any different or subsequent breach.

(f) **Effect on Master Agreement.** This BAA together with the Master Agreement constitutes the complete agreement between the Parties and supersedes all prior representations or agreements, whether oral or written, with respect to such matters. In the event of any conflict between the terms of this BAA and the terms of the Master Agreement, the terms of this BAA shall control unless the terms of such Master Agreement are stricter, as determined by Covered Entity, with respect to PHI and comply with HIPAA, or the Parties specifically otherwise agree in writing. No oral modification or waiver of any of the provisions of this BAA shall be binding on either party. No obligation on either party to enter into any transaction is to be implied from the execution or delivery of this BAA.

(g) **Interpretation.** Any ambiguity in this BAA shall be resolved to permit the Covered Entity to comply with HIPAA and any subsequent guidance.

(h) **No Third Party Rights.** Except as stated herein, the terms of this BAA are not intended nor should they be construed to grant any rights, remedies, obligations, or liabilities whatsoever to parties other than Business Associate and Covered Entity and their respective successors or assigns.

(i) **Applicable Law.** This BAA shall be governed under the laws of the State of Delaware, without regard to choice of law principles, and the Delaware courts shall have sole and exclusive jurisdiction over any dispute arising under this Agreement.

(j) **Judicial and Administrative Proceedings.** In the event that Business Associate receives a subpoena, court or administrative order, or other discovery request or mandate for release of PHI, Business Associate agrees to collaborate with Covered Entity with respect to Business Associate's response to such request. Business Associate shall notify Covered Entity within seven (7) days of receipt of such request or mandate.

(k) **Transmitting Electronic PHI.** Electronic PHI transmitted or otherwise transferred from between Covered Entity and Business Associate must be encrypted by a process that renders the Electronic PHI unusable, unreadable, or indecipherable to unauthorized

individuals within the meaning of HITECH Act § 13402 and any implementing guidance including, but not limited to, 42 C.F.R. § 164.402.

6. IN WITNESS WHEREOF, the Parties hereto have executed this BAA to be effective on the date set forth above.

Covered Entity

Business Associate

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____