ATTACHMENT 07

BUSINESS ASSOCIATE ADDENDUM

BETWEEN

Division of Public and Behavioral Health

Program/Agency name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Hereinafter referred to as the “Covered Entity”

and

Vendor name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Hereinafter referred to as the “Business Associate”

PURPOSE. In order to comply with the requirements of HIPAA and the HITECH Act, this Addendum is hereby added and made part of the Contract between the Covered Entity and the Business Associate. This Addendum establishes the obligations of the Business Associate and the Covered Entity as well as the permitted uses and disclosures by the Business Associate of protected health information it may possess by reason of the Contract. The Covered Entity and the Business Associate shall protect the privacy and provide for the security of protected health information disclosed to the Business Associate pursuant to the Contract and in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-5 (“the HITECH Act”), and regulation promulgated there under by the U.S. Department of Health and Human Services (the “HIPAA Regulations”) and other applicable laws.

WHEREAS, the Business Associate will provide certain services to the Covered Entity, and, pursuant to such arrangement, the Business Associate is considered a business associate of the Covered Entity as defined in HIPAA, the HITECH Act, the Privacy Rule and Security Rule; and

WHEREAS, Business Associate may have access to and/or receive from the Covered Entity certain protected health information, in fulfilling its responsibilities under such arrangement; and

WHEREAS, the HIPAA Regulations, the HITECH Act, the Privacy Rule and the Security Rule require the Covered Entity to enter into a contract containing specific requirements of the Business Associate prior to the disclosure of protected health information, as set forth in, but not limited to, 45 CFR Parts 160 & 164 and Public Law 111-5.

THEREFORE, in consideration of the mutual obligations below and the exchange of information pursuant to this Addendum, and to protect the interests of both Parties, the Parties agree to all provisions of this Addendum.

## **DEFINITIONS**

The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in the context in which they first appear.

1. **Breach** means the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of the protected health information. The full definition of breach can be found in 42 USC 17921 and 45 CFR 164.402.
2. **Business Associate** shall mean the name of the organization or entity listed above and shall have the meaning given to the term under the Privacy and Security Rule and the HITECH Act. For full definition refer to 45 CFR 160.103.
3. **CFR** stands for the Code of Federal Regulations.
4. **Contract** shall refer to this Addendum and that particular Contract to which this Addendum is made a part.
5. **Covered Entity** shall meanthe name of the Division listed above and shall have the meaning given to such term under the Privacy Rule and the Security Rule, including, but not limited to 45 CFR 160.103.
6. **Designated Record Set** means a group of records that includes protected health information and is maintained by or for a covered entity or the Business Associate that includes, but is not limited to, medical, billing, enrollment, payment, claims adjudication, and case or medical management records. Refer to 45 CFR 164.501 for the complete definition.
7. **Disclosure** means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information as defined in 45 CFR 160.103.
8. **Electronic Protected Health Information** means individually identifiable health information transmitted by electronic media or maintained in electronic media as set forth under 45 CFR 160.103.
9. **Electronic Health Record** means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff. Refer to 42 USC 17921.
10. **Health Care Operations** shall have the meaning given to the term under the Privacy Rule at 45 CFR 164.501.
11. **Individual** means the person who is the subject of protected health information andis defined in 45 CFR 160.103.
12. **Individually Identifiable Health Information** means health information, in any form or medium, including demographic information collected from an individual, that is created or received by a covered entity or a business associate of the covered entity and relates to the past, present, or future care of the individual. Individually identifiable health information is information that identifies the individual directly or there is a reasonable basis to believe the information can be used to identify the individual. Refer to 45 CFR 160.103.
13. **Parties** shall mean the Business Associate and the Covered Entity.
14. **Privacy Rule** shall mean the HIPAA Regulation that is codified at 45 CFR Parts 160 and 164, Subparts A, D and E.
15. **Protected Health Information** means individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. Refer to 45 CFR 160.103 for the complete definition.
16. **Required by Law** means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. This includes, but is not limited to: court orders and court-ordered warrants; subpoenas, or summons issued by a court; and statues or regulations that require the provision of information if payment is sought under a government program providing public benefits. For the complete definition refer to 45 CFR 164.103.
17. **Secretary** shall mean the Secretary of the federal Department of Health and Human Services (HHS) or the Secretary’s designee.
18. **Security Rule** shall mean the HIPAA regulation that is codified at 45 CFR Parts 160 and 164 Subparts A and C.
19. **Unsecured Protected Health Information** means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in the guidance issued in Public Law 111-5. Refer to 42 USC 17932 and 45 CFR 164.402.
20. **USC** stands for the United States Code.

## **OBLIGATIONS OF THE BUSINESS ASSOCIATE.**

1. **Access to Protected Health Information.** The Business Associate will provide, as directed by the Covered Entity, an individual or the Covered Entity access to inspect or obtain a copy of protected health information about the Individual that is maintained in a designated record set by the Business Associate or, its agents or subcontractors, in order to meet the requirements of the Privacy Rule, including, but not limited to 45 CFR 164.524 and 164.504(e) (2) (ii) (E). If the Business Associate maintains an electronic health record, the Business Associate or, its agents or subcontractors shall provide such information in electronic format to enable the Covered Entity to fulfill its obligations under the HITECH Act, including, but not limited to 42 USC 17935.
2. **Access to Records.** The Business Associate shall make its internal practices, books and records relating to the use and disclosure of protected health information available to the Covered Entity and to the Secretary for purposes of determining Business Associate’s compliance with the Privacy and Security Rule in accordance with 45 CFR 164.504(e)(2)(ii)(H).
3. **Accounting of Disclosures.** Promptly,upon request by the Covered Entity or individual for an accounting of disclosures, the Business Associate and its agents or subcontractors shall make available to the Covered Entity or the individual information required to provide an accounting of disclosures in accordance with 45 CFR 164.528, and the HITECH Act, including, but not limited to 42 USC 17935. The accounting of disclosures, whether electronic or other media, must include the requirements as outlined under 45 CFR 164.528(b).
4. **Agents and Subcontractors.** The Business Associate must ensure all agents and subcontractors to whom it provides protected health information agree in writing to the same restrictions and conditions that apply to the Business Associate with respect to all protected health information accessed, maintained, created, retained, modified, recorded, stored, destroyed, or otherwise held, transmitted, used or disclosed by the agent or subcontractor. The Business Associate must implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation as outlined under 45 CFR 164.530(f) and 164.530(e)(1).
5. **Amendment of Protected Health Information.** The Business Associate will make available protected health information for amendment and incorporate any amendments in the designated record set maintained by the Business Associate or, its agents or subcontractors, as directed by the Covered Entity or an individual, in order to meet the requirements of the Privacy Rule, including, but not limited to, 45 CFR 164.526.
6. **Audits, Investigations, and Enforcement.** TheBusiness Associate must notify the Covered Entity immediately upon learning the Business Associate has become the subject of an audit, compliance review, or complaint investigation by the Office of Civil Rights or any other federal or state oversight agency. The Business Associate shall provide the Covered Entity with a copy of any protected health information that the Business Associate provides to the Secretary or other federal or state oversight agency concurrently with providing such information to the Secretary or other federal or state oversight agency. The Business Associate and individuals associated with the Business Associate are solely responsible for all civil and criminal penalties assessed as a result of an audit, breach, or violation of HIPAA or HITECH laws or regulations. Reference 42 USC 17937.
7. **Breach or Other Improper Access, Use or Disclosure Reporting.** The Business Associate must report to the Covered Entity, in writing, any access, use or disclosure of protected health information not permitted by the Contract, Addendum or the Privacy and Security Rules. The Covered Entity must be notified immediately upon discovery or the first day such breach or suspected breach is known to the Business Associate or by exercising reasonable diligence would have been known by the Business Associate in accordance with 45 CFR 164.410, 164.504(e)(2)(ii)(C) and 164.308(b) and 42 USC 17921. The Business Associate must report any improper access, use or disclosure of protected health information by: The Business Associate or its agents or subcontractors. In the event of a breach or suspected breach of protected health information, the report to the Covered Entity must be in writing and include the following: a brief description of the incident; the date of the incident; the date the incident was discovered by the Business Associate; a thorough description of the unsecured protected health information that was involved in the incident; the number of individuals whose protected health information was involved in the incident; and the steps the Business Associate is taking to investigate the incident and to protect against further incidents. The Covered Entity will determine if a breach of unsecured protected health information has occurred and will notify the Business Associate of the determination. If a breach of unsecured protected health information is determined, the Business Associate must take prompt corrective action to cure any such deficiencies and mitigate any significant harm that may have occurred to individual(s) whose information was disclosed inappropriately.
8. **Breach Notification Requirements.**  If the Covered Entity determines a breach of unsecured protected health information by the Business Associate has occurred, the Business Associate will be responsible for notifying the individuals whose unsecured protected health information was breached in accordance with 42 USC 17932 and 45 CFR 164.404 through 164.406. The Business Associate must provide evidence to the Covered Entity that appropriate notifications to individuals and/or media, when necessary, as specified in 45 CFR 164.404 and 45 CFR 164.406 has occurred. The Business Associate is responsible for all costs associated with notification to individuals, the media or others as well as costs associated with mitigating future breaches. The Business Associate must notify the Secretary of all breaches in accordance with 45 CFR 164.408 and must provide the Covered Entity with a copy of all notifications made to the Secretary.
9. **Breach Pattern or Practice by Covered Entity.** Pursuant to 42 USC 17934, if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material breach or violation of the Covered Entity’s obligations under the Contract or Addendum, the Business Associate must immediately report the problem to the Secretary.
10. **Data Ownership.** The Business Associate acknowledges that the Business Associate or its agents or subcontractors have no ownership rights with respect to the protected health information it accesses, maintains, creates, retains, modifies, records, stores, destroys, or otherwise holds, transmits, uses or discloses.
11. **Litigation or Administrative Proceedings.** The Business Associate shall make itself, any subcontractors, employees, or agents assisting the Business Associate in the performance of its obligations under the Contract or Addendum, available to the Covered Entity, at no cost to the Covered Entity, to testify as witnesses, or otherwise, in the event litigation or administrative proceedings are commenced against the Covered Entity, its administrators or workforce members upon a claimed violation of HIPAA, the Privacy and Security Rule, the HITECH Act, or other laws relating to security and privacy.
12. **Minimum Necessary.** The Business Associate and its agents and subcontractors shall request, use and disclose only the minimum amount of protected health information necessary to accomplish the purpose of the request, use or disclosure in accordance with 42 USC 17935 and 45 CFR 164.514(d)(3).
13. **Policies and Procedures.** The Business Associate must adopt written privacy and security policies and procedures and documentation standards to meet the requirements of HIPAA and the HITECH Act as described in 45 CFR 164.316 and 42 USC 17931.
14. **Privacy and Security Officer(s).** The Business Associate must appoint Privacy and Security Officer(s) whose responsibilities shall include: monitoring the Privacy and Security compliance of the Business Associate; development and implementation of the Business Associate’s HIPAA Privacy and Security policies and procedures; establishment of Privacy and Security training programs; and development and implementation of an incident risk assessment and response plan in the event the Business Associate sustains a breach or suspected breach of protected health information.
15. **Safeguards.** The Business Associate must implement safeguards as necessary to protect the confidentiality, integrity, and availability of the protected health information the Business Associate accesses, maintains, creates, retains, modifies, records, stores, destroys, or otherwise holds, transmits, uses or discloses on behalf of the Covered Entity. Safeguards must include administrative safeguards (e.g., risk analysis and designation of security official), physical safeguards (e.g., facility access controls and workstation security), and technical safeguards (e.g., access controls and audit controls) to the confidentiality, integrity and availability of the protected health information, in accordance with 45 CFR 164.308, 164.310, 164.312, 164.316 and 164.504(e)(2)(ii)(B). Sections 164.308, 164.310 and 164.312 of the CFR apply to the Business Associate of the Covered Entity in the same manner that such sections apply to the Covered Entity. Technical safeguards must meet the standards set forth by the guidelines of the National Institute of Standards and Technology (NIST). The Business Associate agrees to only use, or disclose protected health information as provided for by the Contract and Addendum and to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate, of a use or disclosure, in violation of the requirements of this Addendum as outlined under 45 CFR 164.530(e)(2)(f).
16. **Training.** The Business Associate must train all members of its workforce on the policies and procedures associated with safeguarding protected health information. This includes, at a minimum, training that covers the technical, physical and administrative safeguards needed to prevent inappropriate uses or disclosures of protected health information; training to prevent any intentional or unintentional use or disclosure that is a violation of HIPAA regulations at 45 CFR 160 and 164 and Public Law 111-5; and training that emphasizes the criminal and civil penalties related to HIPAA breaches or inappropriate uses or disclosures of protected health information. Workforce training of new employees must be completed within 30 days of the date of hire and all employees must be trained at least annually. The Business Associate must maintain written records for a period of six years. These records must document each employee that received training and the date the training was provided or received.
17. **Use and Disclosure of Protected Health Information.** The Business Associate must not use or further disclose protected health information other than as permitted or required by the Contract or as required by law. The Business Associate must not use or further disclose protected health information in a manner that would violate the requirements of the HIPAA Privacy and Security Rule and the HITECH Act.

## **PERMITTED AND PROHIBITED USES AND DISCLOSURES BY THE BUSINESS ASSOCIATE**

The Business Associate agrees to these general use and disclosure provisions:

* 1. **Permitted Uses and Disclosures:**
     1. Except as otherwise limited in this Addendum, the Business Associate may use or disclose protected health information to perform functions, activities, or services for, or on behalf of, the Covered Entity as specified in the Contract, provided that such use or disclosure would not violate the HIPAA Privacy and Security Rule or the HITECH Act, if done by the Covered Entity in accordance with 45 CFR 164.504(e) (2) (i) and 42 USC 17935 and 17936.
     2. Except as otherwise limited by this Addendum, the Business Associate may use or disclose protected health information received by the Business Associate in its capacity as a Business Associate of the Covered Entity, as necessary, for the proper management and administration of the Business Associate, to carry out the legal responsibilities of the Business Associate, as required by law or for data aggregation purposes in accordance with 45 CFR 164.504(e)(2)(A), 164.504(e)(4)(i)(A), and 164.504(e)(2)(i)(B).
     3. Except as otherwise limited in this Addendum, if the Business Associate discloses protected health information to a third party, the Business Associate must obtain, prior to making any such disclosure, reasonable written assurances from the third party that such protected health information will be held confidential pursuant to this Addendum and only disclosed as required by law or for the purposes for which it was disclosed to the third party. The written agreement from the third party must include requirements to immediately notify the Business Associate of any breaches of confidentiality of protected health information to the extent it has obtained knowledge of such breach. Refer to 45 CFR 164.502 and 164.504 and 42 USC 17934.
     4. The Business Associate may use or disclose protected health information to report violations of law to appropriate federal and state authorities, consistent with 45 CFR 164.502(j)(1).
  2. **Prohibited Uses and Disclosures:**

a. Except as otherwise limited in this Addendum, the Business Associate shall not disclose protected health information to a health plan for payment or health care operations purposes if the patient has required this special restriction and has paid out of pocket in full for the health care item or service to which the protected health information relates in accordance with 42 USC 17935.

b. The Business Associate shall not directly or indirectly receive remuneration in exchange for any protected health information, as specified by 42 USC 17935, unless the Covered Entity obtained a valid authorization, in accordance with 45 CFR 164.508 that includes a specification that protected health information can be exchanged for remuneration.

## **OBLIGATIONS OF COVERED ENTITY**

1. The Covered Entity will inform the Business Associate of any limitations in the Covered Entity’s Notice of Privacy Practices in accordance with 45 CFR 164.520, to the extent that such limitation may affect the Business Associate’s use or disclosure of protected health information.
2. The Covered Entity will inform the Business Associate of any changes in, or revocation of, permission by an individual to use or disclose protected health information, to the extent that such changes may affect the Business Associate’s use or disclosure of protected health information.
3. The Covered Entity will inform the Business Associate of any restriction to the use or disclosure of protected health information that the Covered Entity has agreed to in accordance with 45 CFR 164.522 and 42 USC 17935, to the extent that such restriction may affect the Business Associate’s use or disclosure of protected health information.
4. Except in the event of lawful data aggregation or management and administrative activities, the Covered Entity shall not request the Business Associate to use or disclose protected health information in any manner that would not be permissible under the HIPAA Privacy and Security Rule and the HITECH Act, if done by the Covered Entity.

## **TERM AND TERMINATION**

1. **Effect of Termination**:
   1. Except as provided in paragraph (b) of this section, upon termination of this Addendum, for any reason, the Business Associate will return or destroy all protected health information received from the Covered Entity or created, maintained, or received by the Business Associate on behalf of the Covered Entity that the Business Associate still maintains in any form and the Business Associate will retain no copies of such information.
   2. If the Business Associate determines that returning or destroying the protected health information is not feasible, the Business Associate will provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon a mutual determination that return, or destruction of protected health information is infeasible, the Business Associate shall extend the protections of this Addendum to such protected health information and limit further uses and disclosures of such protected health information to those purposes that make return or destruction infeasible, for so long as the Business Associate maintains such protected health information.
   3. These termination provisions will apply to protected health information that is in the possession of subcontractors, agents, or employees of the Business Associate.
2. **Term**. The Term of this Addendum shall commence as of the effective date of this Addendum herein and shall extend beyond the termination of the contract and shall terminate when all the protected health information provided by the Covered Entity to the Business Associate, or accessed, maintained, created, retained, modified, recorded, stored, or otherwise held, transmitted, used or disclosed by the Business Associate on behalf of the Covered Entity, is destroyed or returned to the Covered Entity, or, if it not feasible to return or destroy the protected health information, protections are extended to such information, in accordance with the termination.
3. **Termination for Breach of Contract**. The Business Associate agrees that the Covered Entity may immediately terminate the Contract if the Covered Entity determines that the Business Associate has violated a material part of this Addendum.

## **MISCELLANEOUS**

1. **Amendment.** The parties agree to take such action as is necessary to amend this Addendum from time to time for the Covered Entity to comply with all the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law No. 104-191 and the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009, Public Law No. 111-5.
2. **Clarification.** This Addendum references the requirements of HIPAA, the HITECH Act, the Privacy Rule and the Security Rule, as well as amendments and/or provisions that are currently in place and any that may be forthcoming.
3. **Interpretation.** The provisions of the Addendum shall prevail over any provisions in the Contract that may conflict or appear inconsistent with any provision in this Addendum. This Addendum and the Contract shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule. The parties agree that any ambiguity in this Addendum shall be resolved to permit the Covered Entity and the Business Associate to comply with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule.
4. **Regulatory Reference.** A reference in this Addendum to a section of the HITECH Act, HIPAA, the Privacy Rule and Security Rule means the sections as in effect or as amended.
5. **Survival**. The respective rights and obligations of Business Associate under Effect of Termination of this Addendum shall survive the termination of this Addendum.

**IN WITNESS WHEREOF**, the Business Associate and the Covered Entity have agreed to the terms of the above written agreement.

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| Authorized Signature | Date |  | Title |

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

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|  |  |  | Administrator, DPBH |
| Cody Phinney | Date |  | Title |