

BUSINESS ASSOCIATE AGREEMENT

1. BACKGROUND AND PURPOSE. The parties have entered into, and may in the future enter into, one or more written agreements, that require Company to create, receive, maintain and/or transit "protected health information". The parties enter into this Business Associate Agreement (the "Agreement") to comply with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-91, as amended ("HIPAA"), and the Privacy, Security, Breach Notification, Enforcement and Electronic Transactions Rules at 45 C.F.R. Part 160, Part 162 and Part 164 (collectively the "HIPAA Rules"). The Agreement implements applicable provisions of the Health Information Technology for Economic and Clinical Health Act passed as part of the American Recovery and Reinstatement Act of 2009, as may be amended (the "HITECH Act"), and related regulations published in the Federal Register on January 25, 2013.

This BAA shall supplement and/or amend each of the Underlying Contract(s) only with respect to Company's Use, Disclosure, and creation of PHI under the Underlying Contract(s) to allow Covered Entity to comply with the HIPAA Laws. Except as so supplemented and/or amended, the terms of the Underlying Contract(s) shall continue unchanged and shall apply with full force and effect to govern the matters addressed in this BAA and in each of the Underlying Contract(s).

2. **DEFINITIONS.** Unless otherwise defined in this BAA, all capitalized terms used in this BAA have the meanings ascribed in the HIPAA Laws; provided, however, "Administrative Safeguards" shall have the same meaning as the term "administrative safeguards" in 45 C.F.R. § 164.304, with the exception that it shall apply to the management of the conduct of Company's workforce, not Covered Entity's workforce, in relation to the protection of that information.

2.1 "Minimum Necessary" means the minimum amount of PHI necessary to accomplish the intended purpose of the use, disclosure, ore request or the amount of PHI described and defined by HHS from time to time as the "minimum necessary".

2.2 Other terms. All other terms not specifically defined in this Agreement shall have the meanings attributed to them under HIPAA.

3. OBLIGATIONS OF THE PARTIES WITH RESPECT TO PHI.

- **3.1. Permitted Uses and Disclosures of PHI.** Except as otherwise specified in this BAA, Company may make any and all Uses and Disclosures of PHI necessary to perform its obligations under the Underlying Contract(s), or as Required by Law. Unless otherwise limited herein, Company may, as a Business Associate of Covered Entity:
 - a. provide Data Aggregation services relating to the Health Care Operations of the Covered Entity; [§ 164.504 (e)(2)(i)(B)]

- b. Use or Disclose PHI as Required by Law;
- c. de-identify any and all PHI obtained by Company under this BAA, and use such deidentified data, all in accordance with the de-identification requirements of the Privacy Rule guidance issued by the Secretary from time to time. [§ 164.502 (d)(1)]
- d. Use or Disclose PHI for the proper management and administration of Company or to carry out the legal responsibilities of Company, pursuant to 45 C.F.R. § 164.504(e)(4), provided that (i) such Use or Disclosure is Required by Law, (ii) Company obtains reasonable assurances from the person or entity which does not qualify as a subcontractor that is a business associate under the Rules and to which Company discloses PHI for such purposes permitted under this Section 3.1(d) that such PHI will be held confidentially, Used or further Disclosed only as required by law or the purpose for which it was disclosed to such person or entity, and that such third party shall notify Company of any instances of which the third party is aware in which the confidentiality of the PHI received pursuant to this provision has been or third party reasonably believes has been breached. [§ 164.502(e)(2)(i)(A); § 164.504 (e)(4)(i) and (ii)]
- e. Under no circumstances may Company Use or further Disclose PHI in a manner that would violate the HIPAA Laws if done by the Covered Entity.
- **3.2. Obligations of Company.** With regard to its Use and/or Disclosure of PHI, Company agrees to:
 - a. Use or Disclose PHI consistent with Covered Entity's minimum necessary policy and in accordance with the HIPAA Laws. [§ 164.502(b)]
 - b. Only Use or further Disclose PHI as allowed or required by this BAA or as Required By Law. [§ 164.504 (e)(2)(ii)(A)]
 - c. use appropriate safeguards and with respect to PHI transmitted by or maintained in Electronic Media, comply with subpart C of 45 C.F.R. Part 164 regarding provisions of the Security Rule applicable to such information, to prevent the Use or Disclosure of PHI other than as provided for by this BAA, including, without limitation, adequate training and education of Company's employees, staff or agents regarding such safeguards as implemented by the Company. [§ 164.504 (e)(2)(ii)(B)]
 - d. report to Covered Entity any Use or Disclosure of PHI not provided for by this BAA of which Company becomes aware, including without limitation Breaches of Unsecured PHI as required by 45 C.F.R. §164.410. [§ 164.504 (e)(2)(ii)(C)]
 - e. ensure that any subcontractor that is a business associate, as included in the definition of Business Associate at 45 C.F.R. 160.103, (each a "Subcontractor") enters into an agreement or similar arrangement which complies with the HIPAA Laws requirements for agreements between "Business Associates" and "Covered Entities", as each term is used under the HIPAA Laws, and subject to the same restrictions and limitations imposed upon Company in this BAA regarding the Use and Disclosure of PHI transmitted, received, created, or maintained by Subcontractor on behalf of Company in its capacity as Business Associate of Covered Entity. [§ 164.504 (e)(2)(ii)(D)]; [§ 164.314 (a)(2)(i) (B)]
 - f. within ten (10) days of receiving a written request from Covered Entity, make available to the Covered Entity such PHI necessary for Covered Entity to comply with its obligations under 45 C.F.R. § 164.524 in responding to an Individual's request for access to his or her PHI where company maintains PHI in a Designated Record Ser. [§ 164.504 (e)(2)(ii)(E)] In the event any individual requests access to PHI directly from Company,

Company shall within five (5) business days forward such request to Covered Entity. Any denials of access to the PHI requested shall be the exclusive responsibility of the Covered Entity.

- g. within twenty (20) days of receiving a written request from Covered Entity, make available to the Covered Entity such PHI necessary for Covered Entity to comply with its obligations under 45 C.F.R. § 164.526 in responding to an Individual's request for amendment and Company shall incorporate any amendments to the PHI as directed or instructed by Covered Entity in accordance with 45 C.F.R. § 164.526 where Company maintains PHI in the Designated Record Set. [§ 164.504 (e)(2)(ii)(F)] In the event any Individual requests an amendment to PHI directly from Company, Company shall within (5) business day forward such request to Covered Entity.
- h. within twenty (20) days of receiving a written request from Covered Entity, make available to the Covered Entity the information required for the Covered Entity to provide an accounting of disclosures of PHI as required by the Privacy Rule. Company shall provide the Covered Entity with the following information: (i) the date of the disclosure, (ii) the name of the entity or person who received the PHI, and if known, the address of such entity or person, (iii) a brief description of the PHI disclosed, and (iv) one of the following, as applicable: (a) a brief statement of the purpose of such disclosure which includes an explanation that reasonably informs the individual of the basis for such disclosure or in lieu of such statement, (b) a copy of a written request from the Secretary of Health and Human Services (the "Secretary") to investigate or determine compliance with HIPAA; (c) a copy of a written request for a disclosure for which an authorization or opportunity to agree or object is not required in accordance with 45 C.F.R. § 164.512, if any; or (d) a copy of the individual's request for an accounting. In the event the request for an accounting is delivered directly to Company, Company shall within seven (7) business days forward such request to the Covered Entity.[§ 164.504 (e)(2)(ii)(G)]. Company shall retain its records regarding Uses and Disclosures of PHI for no less than six (6) years following the termination of this BAA.
- i. to the extent that Company carries out Covered Entity's obligation(s) under Subpart E of 45 C.F.R. Part 164, Company shall comply with the HIPAA Laws that apply to the Covered Entity in performance of such obligation(s), as required under 45 C.F.R. § 164.504(e)(2)(H). [§ 164.504(e)(2)(H)]
- j. notify the Covered Entity within five (5) business days of Company's receipt of any request for production or subpoena of PHI, in connection with any governmental investigation or governmental or civil proceeding. If the Covered Entity decides to challenge the validity of or assume responsibility for responding to such request or subpoena, Company shall cooperate fully with the Covered Entity in connection therewith.
- k. Company agrees to make its internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of received from, or created or received by Company on behalf of Covered Entity available to Covered Entity or to the Secretary, for purposes of determining Covered Entity's compliance with the HIPAA Laws. [§ 164.504 (e)(2)(ii)(I)]
- 1. use reasonable commercial efforts to mitigate any harmful effect that is known to Company of a Use or Disclosure of PHI by Company in violation of the requirements of this BAA.

- m. Company agrees to use appropriate safeguards to prevent any unauthorized or unlawful Use, access or Disclosure of the PHI, including but not limited to any Use, access or Disclosure not provided for by this BAA. Company shall implement administrative, physical and technical safeguards and comply with the policies, procedures and documentation requirements of the Security Rule. [§ 164.314 (a)(2)(i)(A)]
- n. report promptly and without unreasonable delay to Covered Entity any Use or Disclosure of PHI not provided for or permitted by this BAA and any Security Incident, including without limitation Breaches of Unsecured PHI, of which Company becomes aware [§ 164.314 (a)(2)(i)(C)].
- o. following the Discovery of a Breach, Company shall notify Covered Entity without unreasonable delay but in no event more than ten (10) business days after discovery of such Breach. Such notification shall include the following information which shall be supplemented as such information becomes available (i) the identification of each Individual whose Unsecured PHI has been, or is reasonably believed by Company to have been accessed, acquired, used or disclosed during the Breach; [§ 164.410(c)(i)] and (ii) each of the elements of a required notification to the Individual as set forth under Section 45 C.F.R. § 164.404(c). [§ 164.410(c)(ii)]. Where Company performs a Risk Assessment in accordance with § 45 C.F. R. § 164.502 and determines a Breach has not occurred because of the low probability the PHI has been compromised, Company will maintain sufficient documentation supporting this determination and make such documentation available to Covered Entity upon reasonable request. Company shall retain such documentation for a period of six (6) years following the termination of this BAA.

4. OBLIGATIONS OF COVERED ENTITY.

4.1 Covered Entity agrees not to request Company to Use or Disclose PHI in any manner that would not be permissible under Subpart E of 45 C.F.R. Part 164 if done by the Covered Entity. [§164.504(e)(2)(i)]

2. Covered Entity shall notify Company of any restriction on the use or disclosure of PHI to which Covered Entity has agreed in accordance with the relevant provisions of HIPAA, to the extent that such restriction may affect Company's use or disclosure of PHI.

3. Covered Entity agrees to notify Company 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 Company's use or disclosure of PHI.

4. Covered Entity shall notify Company of any changes in, or revocation of, permission by an individual to use or disclose such individual's PHI to the extent that such change may affect Company's use or disclosure of PHI.

- **5. TERM.** This BAA shall commence as of the Effective Date and expire, unless earlier terminated pursuant to Section 6 hereof, at such time as the Underlying Agreement(s) is terminated or expires and Company returns or destroys PHI in accordance with the terms of this BAA.
- 6. **TERMINATION BY COVERED ENTITY.** Should Covered Entity become aware of a material breach of this BAA, including without limitation a pattern of activity or practice that constitutes a material breach of a material term of this BAA by Company, the Covered Entity shall provide Company with written notice of such breach in sufficient detail to enable Company to understand the specific nature of

the breach. Covered Entity shall be entitled to immediately terminate this BAA and the Underlying Contract associated with such breach if, after Covered Entity provides such notice of breach to Company, Company fails to cure the breach within a reasonable time period not to exceed thirty (30) days from Company's receipt of such notice; provided, however, Covered Entity shall have the discretion to agree to such longer cure period based on the nature of the breach involved and subject to the HIPAA Laws. [§ § 164.504 (e)(1)(ii)]

- 7. **RETURN OR DESTRUCTION OF PHI.** Upon the expiration or termination of this BAA and/or the Underlying Contract(s), Company, with respect to PHI received from Covered Entity, or created, maintained or received by Company on behalf of Covered Entity, including any and all PHI in the possession of Company's Subcontractors and such third parties permitted to receive such PHI under and in accordance with the terms of this BAA and the HIPAA Laws, shall:
 - a. retain only that PHI which is necessary for Company to continue its proper management and administration or to carry out its legal responsibilities;
 - b. return to Covered Entity or destroy, as agreed to by Covered Entity, the remaining PHI that Company still maintains in any form;
 - c. continue to use appropriate safeguards and comply with the Security Rule with respect to PHI transmitted by or maintained in Electronic Media to prevent Use or Disclosure of the PHI, other than as provided for in this Section, for as long as Company retains the PHI;
 - d. not Use or Disclose the PHI retained by Company other than for the purposes for which such PHI was retained and subject to the same conditions set forth in Section 3 hereof which applied prior to termination;
 - e. return to Covered Entity or destroy, as agreed to by Covered Entity, the PHI retained by Company when it is no longer needed by Company for its proper management and administration or to carry out its legal responsibilities. [§ 164.504 (e)(2)(ii)(J)]; and
 - f. where the return or destruction of PHI is infeasible, Company shall notify Covered Entity in a writing of sufficient specificity of the circumstances which make such return or destruction infeasible, and upon acceptance and agreement by Covered Entity, Company shall continue to extend the protections of this Agreement to such PHI and limit further use or disclosure of PHI to those purposes which make the return or destruction infeasible, for as long as Company retains the PHI. [§164.504 (e)(2)(ii)(J)]
- 8. INDEMNIFICATION. Company shall indemnify, defend and hold harmless Covered Entity and its employees, directors, officers, subcontractors, agents and affiliates (collective, "Covered Entity Indemnified Parties") from and against all claims, actions, damages, losses, liabilities, fines, costs, expenses (including without limitation reasonable attorney's fees) or penalties (including without limitation whether imposed by a judicial or administrative proceeding or pursuant to the HIPAA Laws) suffered by Covered Entity Indemnified Parties to the extent arising from or in connection with any breach of this BAA, which shall be defined to include without limitation noncompliance with any aspect of the HIPAA Laws applicable to Company as a Business Associate of Covered Entity throughout the term of this BAA, or any negligent or wrongful act or omission in connection with this BAA, by Company or by its employees, directors, agents, or subcontractors, including without limitation its Subcontractors.

9. Additional Obligations.

(a) <u>Electronic Copies of PHI</u>. As applicable, Company will (i) cooperate with Covered Entity to provide an Individual with an electronic copy of such individual's PHI if the PHI is maintained by Company in an electronic health record and the individual requests an electronic copy of his or her PHI; and (ii) cooperate with Covered Entity to facilitate Covered Entity's compliance with its obligations regarding electronic health records pursuant to Section 13405(e)(1) of the HITECH Act and any regulations HHS may promulgate thereunder.

(a) <u>Non-Disclosure for Out-of-Pocket Services</u>. As applicable, Company will (i) abide by any directive from Covered Entity not to disclose PHI in connection with an item or service for which an individual has paid out-of-pocket, in full, and (ii) cooperate with Covered Entity to facilitate Covered Entity's compliance with its obligations not to disclose certain PHI in accordance with Section 13405(a) of the HITECH Act and any regulations HHS may promulgate thereunder.

(b) <u>Prohibition on Sale of PHI</u>. Company will not sell PHI or receive any direct or indirect remuneration in exchange for PHI, except as expressly permitted by this Agreement and the Services Agreement.

(c) <u>Prohibition on Marketing</u>. Company will not transmit, to any individual for whom Company has PHI, any communication about a product or service that encourages the recipient of the communication to purchase or use that product or service unless permitted to do so under the HITECH Act.

9. MISCELLANEOUS.

- 9.1. Applicability. This agreement shall be applicable to PHI received by Company from Covered Entity or created or received by Company on behalf of Covered Entity.
- **9.2.** Survival. The respective rights and obligations of Company and Covered Entity under this BAA which by their nature shall survive this BAA shall survive the expiration or termination of this BAA indefinitely, including without limitation Section 3.2(h) and (o), Section 7, Section 8, and this Section 9.
- **9.3. Interpretation.** The terms of this BAA shall prevail in the case of any conflict with the terms of any Underlying Contract to the extent necessary to allow Covered Entity to comply with the HIPAA Laws. Any ambiguity in this BAA shall be resolved in favor of a meaning that permits Covered Entity to comply with the HIPAA Laws. The bracketed citations to the HIPAA Laws in several paragraphs of this BAA are for reference only and shall not be relevant in interpreting any provision of this BAA.
- **9.4.** No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Covered Entity, Company and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
- **9.5. Conflicts.** The terms and conditions of this Agreement override and control any conflicting term or condition of any other agreements that may be in place between the parties. All non-conflicting terms and conditions of this Agreement and any other agreement between the parties remain in full force and effect.

- **9.6. Construction.** This Agreement shall be construed as broadly as necessary to implement and comply with HIPAA. Any ambiguity in this Agreement shall be resolved in favor of a meaning that complies with HIPAA.
- **9.7. Amendments.** The parties acknowledge that state and federal laws relating to data security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA and other applicable laws relating to the security or confidentiality of PHI.
- **9.8.** Notices. All notices required to be given to either party under this Agreement will be in writing and sent by traceable carrier to each party's address indicated below, or such other address as a party may indicate by at least ten (10) days' prior written notice to the other party. Notices will be effective upon receipt.

COVERED ENTITY Fairhope Pediatrics, Inc. 19087-B Greeno Road Fairhope, AL 36532

COMPANY

- **9.9.** Waiver. A waiver with respect to one event will not be construed as continuing, or as a bar or waiver of any right or remedy as to subsequent events.
- **9.10.** Counterparts; Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute but one and the same instrument. Any signature delivered via facsimile shall be deemed to be an original signature hereto.
- **9.11.** Governing Law. The Parties hereby agree that this BAA shall be governed by, and in construed in accordance with, the laws of the Alabama, without giving effect to its conflicts of laws principles and hereby submit themselves to the jurisdiction and venue of the federal and state courts of Alabama.

[Signatures on following page]

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

COMPANY
By:
Print Name:
Print Title:
Date:

HIPAA Glossary Additions

"Electronic format" is a format from which a government agency is able to generate an accurate and complete paper copy that is both legible (**"human readable"**) and suitable for inspection, review, and copying.

The Food and Drug Administration (FDA) advises that documents submitted in electronic format should:

- Enable the user to easily view a clear and legible copy of the information
- •Enable the user to print each document page by page, as it would have been provided in paper, maintaining fonts, special orientations, table formats, and page numbers
- Include a well-structured table of contents and allow the user to navigate easily through the submission Allow the user to copy text and images electronically into common word processing documents

The FDA suggests that electronic documents required to be submitted in electronic format in be submitted in Portable Document Format (PDF). PDF is an open, published format created by Adobe Systems Incorporated (http://www.adobe.com). PDF has been accepted as a standard for providing documents in electronic format by the International Conference on Harmonisation (ICH).

"Limited Data Set (LDS)" is a set of data that lacks 16 of the 18 identifiers itemized by the Privacy Rule. Specifically, a LDS does NOT include the following identifiers:

Name;

Postal address information, other than town or city, State, and zip codes; Telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; and Full face photographic images and any comparable images.

An LDS may contain, for example:

Dates of birth Dates of death Dates of service Town or city State Zip code

A Covered Entity may use or disclose a LDS only for the <u>purposes of research</u>, public health, or <u>health care</u> <u>operations</u> (45 CFR § 164.514(e)(3)(i)). Disclosure of a LDS is an exception to the Privacy Rule requirement to obtain an authorization from the patient (subject) for research use of protected health information.

"Personal Health Record" or "**PHR**" is an electronic record of identifiable health information about an individual that can be drawn from multiple sources and that is managed, shared and controlled by or primarily for the individual by a PHR vendor.

"PHR identifiable health information" is PHI held by a PHR vendor or third party service provider.

"PHI" is protected health information

"Sale of PHI" is the "direct or indirect" receipt of remuneration in exchange for any PHI of an individual.

"Third party service provider" is an entity that provides services to the PHR vendor in connection with the offering or maintenance of a PHR *or* a related product or service *and* that "accesses, maintains, retains,

modifies, records, stores, destroys, or otherwise holds, uses or discloses unsecured PHR identifiable health information in such a record as a result of such services."

"Unsecured PHI (HITECH)" is protected health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals.

HHS guidance released April 17, 2009 identifies two methods by which PHI can be "secured"—encryption or destruction.

- Encryption: Whether or not PHI is properly encrypted depends on the strength of the encryption algorithm and the security of the decryption key or process. HHS released a list of the only acceptable encryption methodologies. Methods not specified in the guidance will not be considered sufficient to render PHI "secured."
- **Destruction:** Hard copies of PHI will only be considered destroyed if they are unreadable and cannot be reconstructed. Electronic media must be cleared, purged or destroyed consistent with standards described in publications issued by the National Institute of Standards and Technology.

1. <u>Definitions</u>. For purposes of this Business Associate Agreement, the following words shall have the following meanings.

1.1 <u>Breach</u> means the acquisition, access, use, or disclosure of Protected Health Information in a manner not permitted under the Privacy Rule which compromises the security or privacy of the Protected Health Information. Breach shall not include:

- (1) Any unintentional acquisition, access, use, or disclosure of Protected Health Information by a workforce member or person acting under the authority of Recipient, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the Privacy Rule; or
- (2) Any inadvertent disclosure by a person who is authorized to access Protected Health Information at Recipient to another person authorized to access Protected Health Information at Recipient, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the Privacy Rule; or
- (3) A disclosure of Protected Health Information where Recipient has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

1.2 Business Associate means a person or organization that (i) creates, receives, maintains, or transmits PHI for the performance of a function or activity on behalf of Covered Entity regulated by the Privacy Regulations, including, without limitation, claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management and repricing; or (ii) provides legal, accounting, consulting, data aggregation, management, administrative, accreditation or financial services to or for Covered Entity, where provision of the services involves the use or disclosure of Protected Health Information. Business Associate includes a subcontractor that creates, receives, maintains, or transmits Protected Health Information on behalf of a Business Associate. A Business Associate does not include a member of the Covered Entity's workforce in his/her capacity as a member of such workforce.

1.3 <u>Covered Entity</u> means a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a standard transaction.

1.4 Designated Record Set means a group of records that are maintained by or for Covered Entity that is

a. the medical records and billing records of an Individual maintained by or for a Covered Entity health care provider; or

- b. the enrollment, payment, claims adjudication, and care or medical management record system maintained by or for a Covered Entity health plan; or
- c. used, in whole or in part, by or for Covered Entity's to make decisions about Individuals.

"Records," as used in this definition, means any item, collection or grouping of information that includes Protected Health Information and is maintained, collected, used or disseminated by or for Covered Entity.

1.5 <u>**Disclosure**</u> means the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside the entity holding such information.

1.6 <u>Electronic PHI</u> means Protected Health Information as defined in this Business Associate Agreement which is (1) transmitted by electronic media, or (2) maintained in electronic media.

1.7 <u>**HITECH Standards**</u> means the privacy, security and Breach notification provisions under Subtitle D of the HITECH Act, and any regulations promulgated thereunder.

1.8 <u>Individual</u> means the person who is the subject of Protected Health Information that the Recipient is provided, receives or otherwise obtains in connection with the performance of its obligations under the Operating Agreement(s).

1.9 <u>Limited Data Set</u> means a set of Protected Health Information that excludes those identifiers listed in 45 CFR 164.514(e)(2) of the Individual or of relatives, employers, or household members of the Individual.

1.10 Privacy Rule means the regulations promulgated by the Secretary to implement the portions of HIPAA that concern the privacy of health information, as may be amended or otherwise changed from time to time. At the date of this Business Associate Agreement, these regulations include 45 CFR §160, Subpart A, and §164, Subparts A, D and E.

1.11 Protected Health Information means information, including demographic information, that (1) relates to (i) a past, present, or future physical or mental health or condition; (ii) the past, present, or future provision of health care; or (iii) the past, present, or future payment for the provision of health care; and (2) identifies the person who is the subject of the information or with respect to which there is a reasonable basis to believe the information can be used to identify such person. Protected Health Information is limited to the information created or received (directly or indirectly) by Recipient from or on behalf of Covered Entity.

1.12 <u>**Recordable Disclosures**</u> includes, but is not limited to, the following disclosures of Protected Health Information permitted by, and as identified in, the Privacy Rule and the HITECH Standards:

- (1) disclosures as Required by Law (including disclosures to the Secretary),
- (2) disclosures for Public Health Activities,
- (3) disclosures about Victims of Abuse, Neglect or Domestic Violence,
- (4) disclosures for Health Oversight Activities,
- (5) disclosures for Judicial and Administrative Proceedings,
- (6) disclosures for Law Enforcement Purposes,
- (7) disclosures about Decedents to Coroners, Medical Examiners and Funeral Directors,
- (8) disclosures for Organ and Transplant Donation Purposes,
- (9) disclosures to Avert a Serious Threat to Health or Safety,
- (10) disclosures for Specialized Government Functions (but excluding such disclosures for national security or intelligence purposes),
- (11) disclosures for Workers' Compensation,
- (12) disclosures for research purposes (i) in accordance with a waiver of authorization granted by an Institutional Review Board or Privacy Board, (ii) in connection with reviews preparatory to research, or (iii) involving decedents. and
- (13) disclosures made, even inadvertently, in violation of this Business Associate Agreement.
- **1.13** <u>Secretary</u> means the Secretary of DHHS or his/her designee.

1.14 <u>Security Rule</u> means the regulations promulgated by the Secretary to implement portions of HIPAA that concern the security of Electronic PHI, as may be amended or otherwise changed from time to time. At the date of this Business Associate Agreement, these regulations include 45 CFR §160, Subpart A, and §164, Subparts A and C.

1.15 <u>Subcontractor</u> means a person to whom a Business Associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such Business Associate.

1.16 <u>Unsecured Protected Health Information</u> 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 regulations or official guidance.

1.17 <u>Use</u> means the sharing, employment, application, utilization, examination, or analysis of Protected Health Information within an entity that maintains such information.

Terms used, but not otherwise defined in this Business Associate Agreement, shall have the same meaning as those terms in the Privacy Rule, the Security Rule and the HITECH Standards as they may be amended from time to time.