

## Business Associate Agreement

This Business Associate Agreement ("BA Agreement") is undertaken pursuant to the parties' performance of a certain contract ("Contract") dated as of \_\_\_\_\_, 20\_\_ by and between the State of Delaware by and through the Department of Health and Social Services on its own behalf (the "Department"), and \_\_\_\_\_ ("Contractor").

In the performance of services on behalf of the Department pursuant to the Contract, and in order for Contractor to use, disclose or create certain information pursuant to the terms of the Contract, some of which may constitute Protected Health Information ("PHI") (defined below), Contractor is a Business Associate of the Department as that term is defined by the Health Insurance Portability and Accountability Act of 1996, including the modifications required under the American Recovery and Reinvestment Act of 2009 ("ARRA"), and its implementing Administrative Simplification regulations (45 C.F.R. §§142, 160, 162 and 164) ("HIPAA"). Accordingly, Contractor, and the Department mutually agree to modify the Contract to incorporate the terms of this BA Agreement to comply with the requirements of HIPAA, and to include additional provisions that the Department and Contractor desire to have as part of the Contract.

Therefore, in consideration of the mutual covenants contained herein and for other good and valuable consideration, the parties agree as follows:

### I. DEFINITIONS

- A. **Covered Entity.** "Covered Entity" means the Client or the client of Client who is a health plan, health care clearinghouse, or a health care provider.
- B. **Individual.** "Individual" shall have the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).
- C. **Required By Law.** "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR 164.501.
- D. **Secretary.** "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.
- E. **Protected Health Information.** "Protected Health Information or "PHI" has the meaning in 45 CFR § 164.501, and is limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- F. **Standard Transactions.** "Standard Transaction(s)" shall mean a transaction that complies with the standards set forth at 45 C.F.R. §162.
- G. **Designated Record Set.** "Designated Record Set" shall have the meaning given to such term in 45 C.F.R. §164.501.
- H. **Summary Health Information.** "Summary Health Information" means information, which may be PHI, (1) that summarizes the history, expenses, or other information experienced by Covered Entities for whom the Department has provided health care benefits and (2) from which the identifiers specified in 45 CFR §164.514(b)(2)(i) have been deleted (except that the zip code information described in 45 CFR §164.514(b)(2)(i)(B) may be aggregated to the level of a five (5) digit zip code).
- I. **Electronic PHI.** "Electronic PHI" shall mean PHI that is subject to the Security Rule, limited to such information created, received, maintained, or transmitted electronically.

- J. **Security Incident.** "Security Incident" shall have the same meaning as "security incident" in 45 CFR 164.304, limited to any such incident involving Electronic PHI.
- K. **Security Rule.** "Security Rule" shall mean the Security Standards for the Protection of Electronic PHI at 45 CFR §§160, 162 and 164.
- L. **Breach.** "Breach" shall mean an unauthorized acquisition, use or disclosure of protected health information (PHI) which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information. For purposes of this definition, "compromises the security or privacy of such information" means poses a significant risk of financial, reputational or other harm to individual.
- M. **Secured PHI.** "Secured PHI" shall mean PHI when it is rendered unusable, unreadable, or indecipherable. Methodologies that render PHI secure are as follows:
- Encryption of electronic data per National Institute Standards and Technology guidelines
  - Destruction of electronic media as per NIST Standards
  - Destruction or shredding of paper, film or other hard copy media
- N. **Unsecured PHI.** "Unsecured PHI" is "unsecure" when it is not rendered unusable, unreadable or indecipherable to authorized individuals through the use of a technology or methodology specified by the Department of Health and Human Services.
- O. All other capitalized terms used in this BA Agreement shall have the meanings set forth in the applicable definitions under the HIPAA Privacy/Security Rule or the Standards for Electronic Transactions.

## II. **PERMITTED USES AND DISCLOSURES BY CONTRACTOR**

- A. During the continuance of the Contract, Contractor will perform services necessary in connection with the Department as outlined in the Contract. These services may include Payment activities, Health Care Operations, and Data Aggregation as these terms are defined in 45 CFR §164.501. In connection with the services to be performed pursuant to the Contract, Contractor is permitted or required to use or disclose PHI it creates or receives for or from the Department or to request PHI on the Department's behalf as provided below.
- B. **Functions and Activities on the Department's Behalf.** Unless otherwise limited in this BA Agreement, Contractor may use or disclose PHI to perform functions, activities, or services for, or on behalf of, the Department as specified in the Contract. Contractor may decide in its own reasonable discretion what uses and disclosures of PHI are required for it to perform administrative services for the Department as outlined in this BA Agreement and in the Contract as well as in accordance with the law.
1. **Use for Contractor's Operations.** Contractor may use PHI it creates or receives for or from the Department for Contractor's proper management and administration or to carry out Contractor's legal responsibilities in connection with services to be provided under the Contract.
  2. **Disclosures for Contractor's Operations.** Contractor may disclose the minimum necessary of such PHI for Contractor's proper management and administration or to carry out Contractor's legal responsibilities, but only if the following conditions are met:
    - a. The disclosure is required by law; or

b. Contractor obtains reasonable assurance, evidenced by written contract, from any person or organization to which Contractor will disclose such PHI that the person or organization will:

- i) Hold such PHI in confidence and use or further disclose it only for the purpose for which Contractor disclosed it to the person or organization or as required by law; and
- ii) Promptly notify Contractor (who will in turn promptly notify the Department) of any instance of which the person or organization becomes aware in which the confidentiality of such PHI was breached.

3. Minimum Necessary Standard. In performing functions and activities in connection with the Contract, Contractor agrees to make reasonable efforts to use, disclose or request only the minimum necessary PHI to accomplish the intended purpose of the use, disclosure or request.

**C. Data Aggregation Services.** The Department agrees and recognizes that Contractor may perform Data Aggregation services for the Department, as defined by the HIPAA Privacy Rule. In the course of performing normal and customary services under the Contract, this data aggregation is an essential part of Contractor's work on behalf of the Department under the Contract. Accordingly, Contractor can perform these data aggregation services in its own discretion, subject to any limitations imposed by the Contract. The term "Data Aggregation" is defined under the HIPAA Privacy Rule to mean, with respect to PHI created or received by a Business Associate in its capacity as the Business Associate of a covered entity, the combining of such PHI by the Business Associate with the PHI received by the Business Associate in its capacity as a Business Associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

**D. Prohibition on Unauthorized Use or Disclosure**

1. Non-permitted Use and Disclosure of PHI. Contractor will neither use nor disclose PHI it creates or receives for or from the Department or from another Business Associate of the Department, except as permitted or required by the Contract and this BA Agreement, as required by law, as otherwise permitted in writing by the Department, as authorized by a Covered Entity.
2. Disclosure to the Department and the Business Associates. To the extent permitted or required by the Contract and this BA Agreement, Contractor will disclose PHI to other Business Associates of the Department which the Department has identified in a writing provided to Contractor. Contractor shall only disclose such PHI to such Business Associates, in their capacity as Business Associates of the Department. Other than disclosures permitted by this Section II or as otherwise specifically identified in the Contract, Contractor will not disclose Covered Entities' PHI to the Department or to a Business Associate of the Department except as directed by the Department in writing.
3. No Disclosure to Department Sponsor. Contractor will not disclose any Covered Entities' PHI to Department Sponsor, except as permitted by and in accordance with Section VIII or as otherwise specifically identified in the Contract.

**III. OBLIGATIONS AND ACTIVITIES OF CONTRACTOR**

- A.** Contractor will develop, document, implement, maintain and use appropriate administrative, technical and physical safeguards to preserve the integrity and confidentiality of, and to prevent non-permitted use or disclosure of, PHI created or received for or from the Department.
- B.** Contractor agrees to mitigate, to the extent practicable, any harmful effect that is known to Contractor of a use or disclosure of PHI by Contractor in violation of the requirements of this BA Agreement.
- C.** Contractor agrees to report to Covered Entity, without unreasonable delay and in any event within 60 days, any use or disclosure of the PHI not provided for by this BA Agreement or otherwise in writing by the Department. Contractor shall maintain a written log recording the date, name of Covered Entity and description of PHI for all such unauthorized use or disclosure and shall submit such log to the Department Sponsor semiannually and by request.
- D.** Contractor will require that any agent, including a subcontractor, to whom it provides PHI as permitted by this BA Agreement (or as otherwise permitted with the Department's prior written approval), agrees to the same restrictions and conditions that apply through this BA Agreement to Contractor with respect to such information.
- E.** Contractor agrees to make internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Contractor on behalf of, Covered Entity available to the Covered Entity, or at the request of the Covered Entity to the Secretary, in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- F.** Contractor agrees to implement administrative, physical, and technical safeguards (as set forth in the Security Rule) that reasonably and appropriately protect the confidentiality and integrity (as set forth in the Security Rule), and the availability of Electronic PHI, if any, that Contractor creates, receives, maintains, or transmits electronically on behalf of Covered Entity. Contractor agrees to establish and maintain security measures sufficient to meet the safe harbor requirements established pursuant to ARRA by making data unreadable, indecipherable, and unusable upon receipt by an unauthorized person. Contractor agrees to provide adequate training to its staff concerning HIPAA and Contractors responsibilities under HIPAA.
- G.** Contractor agrees to report to Covered Entity any Security Incident of which Contractor becomes aware.
- H.** Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides Electronic PHI, agrees to implement reasonable and appropriate safeguards to protect such information.
- I.** Contractor agrees to directly provide notice to any effected participants in the event of a Breach and to send a written log of each such Breach and notice to participants to the covered entity within 30 days of notification. Contractor agrees to notify participants in accordance with the guidelines and standards set forth by the Department of Health and Human Services under the American Reinvestment & Recovery Act and the HITECH Act.

#### IV. INDIVIDUAL RIGHTS OBLIGATIONS

- A. **Access.** Contractor and the Department agree that, wherever feasible, and to the extent that responsive information is in the possession of Contractor, Contractor will provide access to PHI as required by 45 CFR §164.524 on the Department's behalf. Contractor will provide such access according to its own procedures for such access. Contractor represents that its procedures for such access comply with the requirements of 45 CFR §164.524. Such provision of access will not relieve the Department of any additional and independent obligations to provide access where requested by an individual. Accordingly, upon the Department's written or electronic request or the direct request of a Covered Entity or the Covered Entity's Personal Representative, Contractor will make available for inspection and obtaining copies by the Department, or at the Department's direction by the Covered Entity (or the Covered Entity's personal representative), any PHI about the Covered Entity created or received for or from the Department in Contractor's custody or control contained in a Designated Record Set, so that the Department may meet its access obligations under 45 CFR §164.524. All fees related to this access, as determined by Contractor, shall be borne by Covered Entities seeking access to PHI.
- B. **Amendment.** Contractor and the Department agree that, wherever feasible, and to the extent that responsive information is in the possession of Contractor, Contractor will amend PHI as required by 45 CFR §164.526 on the Department's behalf. Contractor will amend such PHI according to its own procedures for such amendment. Contractor represents that its procedures for such amendment comply with the requirements of 45 CFR §164.526. Such amendment will not relieve the Department of any additional and independent obligations to amend PHI where requested by an individual. Accordingly, upon the Department's written or electronic request or the direct request of a Covered Entity or the Covered Entity's Personal Representative, Contractor will amend such PHI contained in a Designated Record Set, in accordance with the requirements of 45 CFR §164.526. Upon receipt of written or electronic notice from the Department, Contractor will amend or permit the Department access to amend any portion of the PHI created or received for or from the Department in Contractor's custody or control, so that the Department may meet its amendment obligations under 45 CFR §164.526.
- C. **Disclosure Accounting.** So that the Department may meet its disclosure accounting obligations under 45 CFR §164.528, Contractor and the Department agree that, wherever feasible and to the extent that disclosures have been made by Contractor, Contractor will provide the accounting that is required under 45 CFR §164.528 on the Department's behalf. Contractor will provide such accounting according to its own procedures for such accounting. Contractor represents that its procedures for such accounting comply with the requirements of 45 CFR §164.528. Such provision of disclosure accounting will not relieve the Department of any additional and independent obligations to provide disclosure accounting where requested by an individual. Accordingly, upon the Department's written or electronic request or the direct request of a Covered Entity or the Covered Entity's Personal Representative, Contractor will provide an accounting as set forth below.

1. **Disclosure Tracking**

Starting as of the Effective Date of the Contract, Contractor will record each disclosure of Covered Entities' PHI, which is not exempted from disclosure accounting that Contractor makes to the Department or to a third party.

The information about each disclosure that Contractor must record ("Disclosure Information") is (a) the disclosure date, (b) the name and (if known) address of the person or entity to whom Contractor made the disclosure, (c) a brief description of the PHI disclosed, and (d) a brief statement of the purpose of the disclosure.

For repetitive disclosures of Covered Entities' PHI that Contractor makes for a single purpose to the same person or entity (including the Department), Contractor may record (a) the Disclosure Information for the first of these repetitive disclosures, (b) the frequency, periodicity or number of these repetitive disclosures, and (c) the date of the last of these repetitive disclosures.

2. Exceptions from Disclosure Tracking

Contractor is not required to record disclosure information or otherwise account for disclosures of PHI that this BA Agreement or the Department in writing permits or requires: (i) for the purpose of the Department's payment activities or health care operations, (ii) to the individual who is the subject of the PHI disclosed, or to that individual's personal representative; (iii) to persons involved in that individual's health care or payment for health care; (iv) for notification for disaster relief purposes, (v) for national security or intelligence purposes, (vi) to law enforcement officials or correctional institutions regarding inmates; (vii) pursuant to an authorization; (viii) for disclosures of certain PHI made as part of a limited data set; (ix) for certain incidental disclosures that may occur where reasonable safeguards have been implemented; (x) for disclosures prior to April 14, 2003; or (xi) as otherwise excepted under 45 CFR §164.528.

3. Disclosure Tracking Time Periods

Contractor will have available for the Department or for Covered Entities the Disclosure Information required for the six (6) years immediately preceding the date of the Department's request for the Disclosure Information (except Contractor will not be required to have Disclosure Information for disclosures occurring before April 14, 2003).

**D. Right to Request Restrictions and Confidential Communications**

So that the Department may meet its obligations to evaluate requests for restrictions and confidential communications in connection with the disclosure of PHI under 45 CFR §164.522, Contractor and the Department agree that, wherever feasible and to the extent that communications are within the control of Contractor, Contractor will perform these evaluations on behalf of the Department. Contractor will evaluate such requests according to its own procedures for such requests, and shall implement such appropriate operational steps as are required by its own procedures. Contractor represents that its procedures for evaluating such requests comply with the requirements of 45 CFR §164.522. Such evaluation will not relieve the Department of any additional and independent obligations to evaluate restrictions or implement confidential communications where requested by an individual. Accordingly, upon the Department's written or electronic request or the direct request of a Covered Entity or the Covered Entity's Personal Representative, Contractor will evaluate requests for restrictions and requests for confidential communications, and will respond to these requests as appropriate under Contractor's procedures.

**V. OBLIGATIONS OF THE COVERED ENTITY**

- A. Covered Entity shall provide Contractor with any changes in, or revocation of, permission by Individual to use or disclose PHI, if such changes affect Contractor's permitted or required uses and disclosures.
- B. Covered Entity shall notify Contractor of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR 164.522.

- C. Covered Entity shall not request Contractor to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity except as provided in this BA Agreement. In no event shall Covered Entity request Contractor to disclose to Covered Entity or agents of Covered Entity any PHI unless such disclosure is the minimum necessary disclosure that satisfies the request and that such disclosure is solely for the purpose of treatment, payment or Department operations.

## VI. BREACH OF PRIVACY OBLIGATIONS

Without limiting the rights of the parties under the Contract, the Department will have the right to terminate the Contract if Contractor has engaged in a pattern of activity or practice that constitutes a material breach or violation of Contractor's obligations regarding PHI under this BA Agreement and, on notice of such material breach or violation from the Department, fails to take reasonable steps to cure the breach or end the violation.

If Contractor fails to cure the material breach or end the violation after the Department's notice, the Department may terminate the Contract by providing Contractor written notice of termination, stating the uncured material breach or violation that provides the basis for the termination and specifying the effective date of the termination. Such termination shall be effective 60 days from this termination notice.

### A. Effect of Termination.

#### 1. Return or Destruction upon Contract End

Upon cancellation, termination, expiration or other conclusion of the Contract, Contractor will if feasible return to the Department or destroy all PHI, in whatever form or medium (including in any electronic medium under Contractor's custody or control), that Contractor created or received for or from the Department, including all copies of such PHI that allow identification of any Covered Entity who is a subject of the PHI. Contractor will complete such return or destruction as promptly as practical after the effective date of the cancellation, termination, expiration or other conclusion of the Contract.

Following notice and good faith negotiation between Contractor and Department as to the reasonable costs, Department will reimburse Contractor's reasonable cost incurred in returning or destroying such PHI subject to the requisite appropriation by the Delaware General Assembly as required by Title 29 Delaware Code Chapter 65 and Article 8, Section III of the Delaware Constitution.

#### 2. Disposition When Return or Destruction Not Feasible

The Department recognizes that in many situations, particularly those involving data aggregation services performed by Contractor for the Department and others, that it will be infeasible for Contractor to return or destroy PHI. Accordingly, where in Contractor's discretion such return or destruction is infeasible, for any such PHI, upon cancellation, termination, expiration or other conclusion of the Contract, Contractor will limit its further use or disclosure of the PHI to those purposes that make their return to the Department or destruction infeasible.

## VII. DEPARTMENT SPONSOR'S PERFORMANCE OF DEPARTMENT ADMINISTRATION FUNCTIONS

- A. Communication of PHI. Except as specifically agreed upon by Contractor, the Department and Department Sponsor, and in compliance with any requirements imposed by this Section

VIII, all disclosures of PHI from Contractor pursuant to the Contract shall be made to the Department.

- B. **Summary Health Information.** Upon Department Sponsor's written request for the purpose to, (a) obtain bids for the Department, or (b) modify, amend or terminate Contractor, Contractor is authorized to provide Summary Health Information regarding the Covered Entities in the Department to Department Sponsor.
- C. **Department Sponsor Representation.** Department Sponsor represents and warrants (A) that the Department has been established and is maintained pursuant to law, (B) that Department provides for the allocation and delegation of responsibilities for the Department, including the responsibilities assigned to Contractor under the Contract, (C) that the Department includes or incorporates by reference the appropriate terms of the Contract and this BA Agreement, and (D) that the Department incorporates the provisions required by 45 CFR §164.504.
- D. **Department Sponsor's Certification.** Contractor will not disclose Covered Entities' PHI to Department Sponsor, unless and until the Department authorizes Contractor in writing to disclose the minimum necessary Covered Entities' PHI to Department Sponsor for the Department administration functions to be performed by Department Sponsor as specified in the Plan.
- E. **Contractor Reliance.** Contractor may rely on Department Sponsor's certification and the Department's written authorization, and will have no obligation to verify that the Department complies with the requirements of 45 CFR §164.504 or this BA Agreement or that Department Sponsor is complying with the Department.
- F. **The Department Amendment.** Before the Department will furnish Department Sponsor's certification described above to Contractor, the Department will ensure (1) that its Department establishes the uses and disclosures of Covered Entities' PHI consistent with the requirements of 45 CFR §164, that Department Sponsor will be permitted and required to make for the Department administration functions Department Sponsor will perform for the Department, and (2) that Department Sponsor agrees to all the applicable conditions imposed by §164.504 on the use or disclosure of PHI.

## VIII. **MISCELLANEOUS**

- A. **Regulatory References.** A reference in this BA Agreement to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.
- B. **Survival.** The respective rights and obligations of Contractor under Section IV of this BA Agreement shall survive the termination of this BA Agreement.
- C. **Interpretation.** Any ambiguity in this BA Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule. Except to the extent specified by this BA Agreement, all of the terms and conditions of the Contract shall be and remain in full force and effect. In the event of any inconsistency or conflict between this BA Agreement and the Contract, the terms and provisions and conditions of this BA Agreement shall govern and control. Nothing express or implied in this BA Agreement and/or in the Contract is intended to confer, nor shall anything herein confer, upon any person other than the parties and the respective successors or assigns of the parties, any rights, remedies, obligations, or liabilities whatsoever. This BA Agreement shall be governed by and construed in accordance with the same internal laws that are applicable to the Contract.
- D. **Duration.** This BA Agreement will continue in full force and effect for as long as the Contract remains in full force and effect. This BA Agreement will terminate upon the cancellation, termination, expiration or other conclusion of the Contract.

- E. Term.** The Term of this BA Agreement shall be effective as of the date appearing on the signature page, and shall terminate when all of the PHI provided by Covered Entity to Contractor, or created or received by Contractor on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions of this BA Agreement.
- F. Amendment.** Upon the effective date of any final regulation or amendment to final regulations with respect to PHI, Standard Transactions, the security of health information or other aspects of HIPAA applicable to this BA Agreement or to the Contract, this BA Agreement will automatically amend such that the obligations imposed on Department Sponsor, the Department and Contractor remain in compliance with such regulations, unless (1) Contractor elects to terminate the Contract by providing Department Sponsor and the Department notice of termination in accordance with the Contract at least thirty (30) days before the effective date of such final regulation or amendment to final regulations; or (2) Contractor notifies the Department of its objections to any such amendment. In the event of such an objection, the parties will negotiate in good faith in connection with such changes or amendment to the relevant final regulation.
- G. Conflicts.** The provisions of this BA Agreement will override and control any conflicting provision of the Contract. All nonconflicting provisions of the Contract will remain in full force and effect.
- H. Independent Relationship.** None of the provisions of this BA 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 as independent parties solely for the purposes of effecting the provisions of this BA Agreement and the Contract.
- I. Rights of Third Parties.** This BA Agreement is between Contractor and the Department and the Department Sponsor and shall not be construed, interpreted, or deemed to confer any rights whatsoever to any third party or parties.
- J. Notices.** All notices and notifications under this BA Agreement shall be sent in writing by traceable carrier to the listed persons on behalf of Contractor, the Department and Department Sponsor at the addresses indicated on the signature page hereof, or such other address as a party may indicate by at least ten (10) days' prior written notice to the other parties. Notices will be effective upon receipt.
- K. Expenses.** Unless otherwise stated in this BA Agreement or the Contract, each party shall bear its own costs and expenses related to compliance with the above provisions. Any additional expenses incurred by Contractor in connection with services to be provided pursuant to this BA Agreement shall be included in the Contract.
- L. Documentation.** All documentation that is required by this BA Agreement or by the HIPAA Privacy Rule must be retained by Contractor for six years from the date of creation or when it was last in effect, whichever is longer.

AGREED By and between the undersigned Parties this \_\_\_\_ day of \_\_\_\_\_ 20\_\_.

**Delaware Department of Health and Social Services:**

**By:** \_\_\_\_\_

**Title:**

\_\_\_\_\_  
**Printed Name**

**Business Associate Name here:**

**By:** \_\_\_\_\_

**Title:**

\_\_\_\_\_  
**Printed Name**