

OPUS

Business Associate Agreement

1. Recitals

A. This Business Associate Agreement is made between you (the “**Business Associate**”) and us (the “**Client**”) on the date accepted by you.

B. The Client is either a “covered entity” or “business associate” of a covered entity (collectively, a “**Covered Entity**”) as each are defined under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the HITECH Act (as defined below) and the related regulations promulgated by HHS (as defined below) (collectively, “**HIPAA**”) and, as such, is required to comply with HIPAA’s provisions regarding the confidentiality and privacy of Protected Health Information.

B. The Parties have entered into or will enter into one or more agreements under which Business Associate provides or will provide certain specified services to Covered Entity (collectively, the “**Agreements**”).

C. In providing services pursuant to the Agreements, Business Associate will have access to Protected Health Information. By providing the services pursuant to the Agreements, Business Associate will become a “business associate” of the Client as such term is defined under HIPAA.

D. Both Parties are committed to complying with all federal and state laws governing the confidentiality and privacy of health information, including, but not limited to, the Standards for Privacy of Individually Identifiable Health Information found at 45 CFR Part 160 and Part 164, Subparts A and E (collectively, the “**Privacy Rule**”); and both Parties intend to protect the privacy and provide for the security of Protected Health Information disclosed to Business Associate pursuant to the terms of this Agreement, HIPAA and other applicable laws.

E. This Business Associate Agreement should be read together with the Agreement(s). To the extent the terms of the agreements conflict, the terms of this Business Associate Agreement shall prevail.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and the continued provision of Protected Health Information by the Client to Business Associate under the Agreements in reliance on this Business Associate Agreement, the Parties agree as follows:

2. Definitions & Interpretation

(a) Interpretation

In this Business Associate Agreement the following rules of interpretation apply unless the contrary intention appears:

- i. headings are for convenience only and do not affect the interpretation of this Business Associate Agreement ;
- ii. the singular includes the plural and vice versa;
- iii. words that are gender neutral or gender specific include each gender;
- iv. where a word or phrase is given a particular meaning, other parts of speech and grammatical forms of that word or phrase have corresponding meanings;

- v. the words "such as", "including", "particularly" and similar expressions are not used as, nor are intended to be interpreted as, words of limitation;
- vi. a reference to:
 - I. a person includes a natural person, partnership, joint venture, government agency, association, corporation, trust or other body corporate;
 - II. a party includes its agents, successors and permitted assigns;
 - III. a document includes all amendments or supplements to that document;
- vii. no rule of construction applies to the disadvantage of a party because that party was responsible for the preparation of this Business Associate Agreement or any part of it.

(b) Catch-all definition:

Terms used, but not otherwise defined, in this Business Associate Agreement shall have the same meaning as those terms in the HIPAA Rules.

The following terms used in this Business Associate Agreement shall have the same meaning as those terms in the HIPAA Rules: **Breach, Business Associate, Covered Entity, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.**

(c) Specific definitions:

- (i) Breach Notification Rule means the portion of HIPAA set forth in Subpart D of 45 CFR Part 164.
- (ii) Business Associate Agreement means this Business Associate Agreement between Business Associate and the Client.
- (iii) Business Day means any calendar day except Saturdays, Sundays or legal holidays in the State of Delaware.
- (iv) Covered Entity shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this Business Associate Agreement, shall mean either the Client (if the Client is a Covered Entity) or to the Covered Entity to whom the Client is subcontracting Business Associate on behalf of (if the Client is a Business Associate).
- (v) HHS means the US Department of Health and Human Services.
- (vi) HIPAA Rules means the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164, as amended by the HITECH Act, and the related regulations promulgated by HHS.
- (vii) HITECH Act means the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, Public Law 111-005.
- (viii) Privacy Rule means that portion of HIPAA set forth in 45 CFR Part 160 and Part 164, Subparts A and E.
- (ix) Security Rule means the Security Standards for the Protection of Electronic Health Information provided in 45 CFR Part 160 & Part 164, Subparts A and C.

3. Obligations and Activities of Business Associate

Business Associate agrees to:

(a) Nondisclosure. Not use or disclose Protected Health Information other than as permitted or required by the Agreements, or as Required By Law and comply with the privacy and security standards and breach notification requirements under federal and state laws, rules and regulations which are applicable to business associates or to Business Associate, including HIPAA, when Using or Disclosing Protected Health Information in any form, including Electronic Protected Health Information, which it creates or receives from or on behalf of Client.

(b) Safeguards. Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic Protected Health Information, to prevent Use or Disclosure of Protected Health Information other than as provided for by the Agreements. Business Associate shall implement and maintain technologies and methodologies that render Protected Health Information unusable, unreadable, or indecipherable to unauthorized individuals as specified by the Secretary in the guidance issue by HHS under Pub. L. 5, § 13402(h)(2) and as are necessary to prevent Protected Health Information from being Used or Disclosed by Business Associate or any of its contractors, subcontractors, Business Associates, or any of their respective employees except as necessary to perform the Services in accordance with the Agreements.

(c) Mitigation. Mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a Use or Disclosure of Protected Health Information by Business Associate or its subcontractors in violation of the requirements of this Business Associate Agreement. Business Associate shall exercise reasonable diligence to discover any Breach of Protected Health Information.

(d) Breach reporting. Report to the Client any Use or Disclosure of Protected Health Information not provided for by the Agreements of which it becomes aware, including Breaches of Unsecured Protected Health Information as required at 45 CFR 164.410, and any Security Incident of which it becomes aware, within 3 Business Days of becoming aware of the Breach or Security Incident. Business Associate further agrees to provide the Client with such information as reasonably required by the Client in relation to the Breach or Security Incident, and use all reasonable endeavors to assist the Client and/or Covered Entity in complying with any relevant notification procedures under the HIPAA Rules.

(e) Subcontractors. In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any Subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of Business Associate agree to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such information. Notwithstanding the foregoing, in no event shall Business Associate disclose Protected Health Information to any Subcontractor without first obtaining satisfactory assurances that the Subcontractor will appropriately safeguard the Protected Health Information in compliance with HIPAA and other applicable laws.

(f) Access to Designated Record Sets. To the extent the Covered Entity or Client determines that any Protected Health Information maintained by Business Associate constitutes a Designated Record Set, make available Protected Health Information to the Covered Entity or Client as necessary to satisfy the Covered Entity's obligations under 45 CFR 164.524, and forward to the Client within 10 Business Days any requests it receives from Individuals for access to their Protected Health Information under 45 CFR 164.524.

(g) Amendments of Designated Record Sets. To the extent the Covered Entity or Client determines that any Protected Health Information maintained by Business Associate constitutes a Designated Record Set, make any amendment(s) to Protected Health Information in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy the Covered Entity's obligations under 45 CFR 164.526, and forward to the Client within 15 Business Days any requests it receives from Individuals for access to their Protected Health Information under 45 CFR 164.526.

(h) Documentation of Disclosures. Maintain and make available the information required to provide an Accounting of Disclosures to the Client as necessary to satisfy the Covered Entity's obligations under 45 CFR 164.528 within 15 Business Days of the information being requested by the Client, and forward to the Client within 15 Business Days after any requests it receives from Individuals for an accounting of Disclosures under 45 CFR 164.528.

(i) Compliance with Law. To the extent Business Associate is to carry out one or more of the Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the Covered Entity in the performance of such obligation(s).

(j) Destruction or Return of Information. When requested by Covered Entity or when this Agreement terminates, Business Associate shall, if feasible, destroy or return to Covered Entity all Protected Health Information and copies of that information in any form that it has received from or on behalf of Covered Entity except as provided herein. If Business Associate destroys the Protected Health Information, it shall, upon request by Covered Entity, certify such destruction in writing to Covered Entity. If it is not feasible to return or destroy the Protected Health Information, Business Associate shall extend the protections of this Agreement to the Protected Health Information retained, and limit further uses and disclosures to those purposes that make return or destruction infeasible for so long as Business Associate maintains such PHI.

(k) Internal Practices. Make its internal practices, books, and records relating to the Use and Disclosure of PHI received from the Client, or created or received by Business Associate on behalf of the Client, available to the Client, Covered Entity, or Secretary for purposes of determining compliance with the HIPAA Rules.

4. Permitted Uses and Disclosures by Business Associate

To the extent required by the HIPAA Rules, Business Associate shall limit its Use, Disclosure, or request of Protected Health Information to the Minimum Necessary to accomplish the intended Use, Disclosure, or request. Subject to this caveat:

(a) Business Associate may Use or Disclose Protected Health Information as necessary to perform the services set forth in the Service Agreement.

(b) Business Associate may Use or Disclose Protected Health Information as Required By Law.

(c) Business Associate agrees to make uses and Disclosures and requests for Protected Health Information consistent with the Client's and the Covered Entity's minimum necessary policies and procedures, as notified to Business Associate.

(d) Business Associate may not use or disclose Protected Health Information in a manner that would violate Subpart E of 45 CFR Part 164 if done by the Covered Entity, except for the specific uses and Disclosures set forth at (e) - (g) below.

(e) Business Associate may use Protected Health Information for the proper management and administration of Business Associate and to carry out the legal responsibilities of Business Associate.

(f) Business Associate may disclose Protected Health Information for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided the Disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as Required By Law or for the purposes for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(g) To the extent permitted by the Agreement(s) or otherwise approved in writing by the Client, and provided that Business Associate otherwise complies with the terms of this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to the Client.

(h) Business Associate may de-identify Protected Health Information so long as the de-identification complies with Section 164.514(b) of the Privacy Regulations, and the Client maintains the documentation required by Section 164.514(b) of the Privacy Regulations, which may be in the form of a written assurance from Business Associate. Such de-identified information is not considered Protected Health Information under the Privacy Regulations.

5. Provisions for Client to Inform Business Associate of Privacy Practices and Restrictions

(a) The Client shall provide Business Associate with the Covered Entity's Notice of Privacy Practices on request, and notify Business Associate of any limitation(s) in the Notice of Privacy Practices of the Covered Entity under 45 CFR 164.520, to the extent that such limitation may affect Business Associate's Use or Disclosure of Protected Health Information.

(b) The Client shall notify Business Associate of any changes in, or revocation of, the permission by an Individual to use or disclose his or her Protected Health Information, to the extent that such changes may affect Business Associate's Use or Disclosure of Protected Health Information.

(c) The Client shall notify Business Associate of any restriction on the Use or Disclosure of Protected Health Information that Covered Entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect Business Associate's use or Disclosure of Protected Health Information.

6. Permissible Requests by Client

Except for data aggregation or management and administrative activities of Business Associate, the Client shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the HIPAA Rules if done by the Client or Covered Entity.

7. Term and Termination

(a) Term. The Term of this Agreement shall be effective from the date accepted by the Client and shall terminate on the termination of the Agreement(s) or on the date the Client terminates as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business Associate authorizes termination of this Agreement by the Client, if Client determines Business Associate has violated a material term of the Agreement and Business Associate has not cured the breach or ended the violation within the time specified by the Client.

(c) Obligations of Business Associate Upon Termination.

Upon termination of this Business Associate Agreement for any reason, Business Associate shall destroy all Protected Health Information received from the Client, or created, maintained, or received by Business Associate on behalf of the Client, that Business Associate still maintains in any form, within 20 Business Days. Business Associate shall retain no copies of the Protected Health Information. Prior to the expiry of this timeframe, the Client may request that Business Associate deliver to it all Protected Health Information received from the Client, or created, maintained, or received by Business Associate on behalf of the Client, that Business Associate still maintains in any form.

If it is determined by Business Associate that it is not feasible to return or destroy any or all of the Protected Health Information, Business Associate must notify the Client of the specific reasons in writing. Business Associate must continue to honor all protections, limitations, and restrictions herein and under applicable law with regard to Business Associate's Use and/or Disclosure of Protected Health Information so retained and to limit any further Uses and/or Disclosures to the specific purposes that render the return or destruction of the Protected Health Information not feasible.

For the avoidance of doubt, the obligations in this subparagraph (c) do not apply to de-identified versions of Protected Health Information produced in accordance with clause 4(h) of this Business Associate Agreement.

The obligations of Business Associate under this section shall survive the termination of this Business Associate Agreement.

8. Representations and warranties

Each Party represents and warrants to the other Party that:

- a. It is duly organized, validly existing, and in good standing under the laws of the state in which it is organized or licensed;
- b. It has the power to enter into this Business Associate Agreement and to perform its duties and obligations hereunder;
- c. All necessary corporate or other actions have been taken to authorize the execution of the Business Associate Agreement and the performance of its duties and obligations;
- d. Neither the execution of this Business Associate Agreement nor the performance of its duties and obligations hereunder will violate any provision of any other agreement, license, corporate charter or bylaws of the Party;
- e. it will not enter into nor perform pursuant to any agreement that would violate or interfere with this Business Associate Agreement;

- f. It is not currently the subject of a voluntary or involuntary petition in bankruptcy, does not currently contemplate filing any such voluntary petition, and is not aware of any claim for the filing of an involuntary petition;
- g. Neither the Party, nor any of its shareholders, members, directors, officers, agents, employees or contractors have been excluded or served a notice of exclusion or have been served with a notice of proposed exclusion, or have committed any acts which are cause for exclusion, from participation in, or had any sanctions, or civil or criminal penalties imposed under, any Federal or state healthcare program, including but not limited to Medicare or Medicaid or have been convicted, under Federal or state law of a criminal offense;
- h. All of its employees, agents, representatives and contractors whose services may use or disclose Protected Health Information on behalf of that Party have been or shall be informed of the terms of this Business Associate Agreement;
- i. All of its employees, agents, representatives and contractors who may use or disclose Protected Health Information on behalf of that Party are under a sufficient legal duty to the respective Party, either by contract or otherwise, to enable the Party to fully comply with all provisions of this Business Associate Agreement.

9. Miscellaneous

(a) Regulatory References. A reference in this Business Associate Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

(b) Amendment. This Business Associate Agreement may be amended by further written agreement, duly signed by authorized representatives of the Parties. The Parties agree to take such action as is necessary to amend this Business Associate Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

(c) Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

(d) Notices. Any notice to the other party pursuant to this Business Associate Agreement must be provided in accordance with the notice requirements in the Agreement(s).

(e) Ownership. Nothing in the Agreements provides Business Associate ownership of Protected Health Information received, maintained, or transmitted by or to Business Associate.

(f) Counterparts. This Business Associate Agreement may be executed in one or more counterparts, including electronic counterparts, each of which will be deemed an original, but all of which together constitute one and the same instrument.

(g) No agency, partnership, or joint venture. Nothing in this Business Associate Agreement shall be construed as creating an agency, partnership, or joint venture relationship between the Parties.

(h) Governing law and jurisdiction. This Business Associate Agreement will be governed by and construed in accordance with the substantive laws of the State of Delaware without regard to conflict of laws and all disputes

arising under or relating to this Agreement shall be brought and resolved solely and exclusively in the State Court located in Delaware.

(i) No waiver. No waiver of any provision of this Business Associate Agreement by either Party shall constitute a general waiver for future purposes.

(j) Severability. If any term or provision of this Business Associate Agreement is found by a court of competent jurisdiction to be invalid, illegal or otherwise unenforceable, the same shall not affect the other terms or provisions hereof or the whole of this Business Associate Agreement, but such term or provision shall be deemed modified to the extent necessary in the court's opinion to render such term or provision enforceable, and the rights and obligations of the parties shall be construed and enforced accordingly, preserving to the fullest permissible extent the intent and agreements of the parties herein set forth.

(m) No third party beneficiaries. Nothing in this Business Associate Agreement shall confer any rights upon any person which is not a party or a successor or permitted assignee of a party to this Agreement.