

Business Associate Agreement

THIS AGREEMENT and commitment is executed by [NAME OF BUSINESS ASSOCIATE] on behalf of [NAME OF COVERED ENTITY]. The effective date of this Business Associate Agreement between [NAME OF BUSINESS ASSOCIATE] and [NAME OF COVERED ENTITY] is set forth in Section 5.

Recitals

[NAME OF BUSINESS ASSOCIATE] and [NAME OF COVERED ENTITY], have a business relationship by virtue of [NATURE OF RELATIONSHIP] with [NAME OF BUSINESS ASSOCIATE] to the [NAME OF COVERED ENTITY], hereinafter, “[NATURE OF RELATIONSHIP].” [NAME OF BUSINESS ASSOCIATE] and [NAME OF COVERED ENTITY] are committed to complying with the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Regulations”) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under the Privacy Regulations, the [NAME OF COVERED ENTITY] is a “Covered Entity,” and, as defined by 45 C.F.R. § 164.502(e) and 45 C.F.R. § 164.504(e), this Business Associate Agreement applies to the extent [NAME OF BUSINESS ASSOCIATE]’s activities fall within the defined activities of a “Business Associate” to the Covered Entity as defined by HIPAA.

Business Associate creates, receives, maintains or transmits Protected Health Information (PHI) in the performance of services under the Insurance Policy. The Covered Entity and Business Associate are required by the Privacy Rule and the Security Rule issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Amendments issued pursuant to the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 to protect the privacy and provide for the security of PHI received by the Business Associate from the Covered Entity, to the extent such disclosure is governed by HIPAA and as amended from time to time, including regulatory amendments of the Department of Health and Human Services published at 78 Fed. Reg. 5566 (Jan. 25, 2013). Business Associate is committed to complying with these statutes, rules and regulations. The Business Associate agrees as follows:

Section 1 Definitions

- 1.1 Breach.** “Breach” shall mean the acquisition, access, use or disclosure of protected health information (PHI) in a manner not permitted under the Privacy Rule which compromises the security or privacy of the PHI. For purposes of this definition, “compromises the security or privacy of the PHI” means poses a significant risk of financial, reputational, or other harm to the individual. A use or disclosure of PHI that does not include the identifiers listed at §164.514(e)(2), limited data set, date of birth, and zip code does not compromise the security or privacy of the PHI.

Breach excludes:

- a. Any unintentional acquisition, access or use of PHI by a workforce member or person acting under the authority of a Covered Entity or Business Associate 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.
- b. Any inadvertent disclosure by a person who is authorized to access PHI at a Covered Entity or Business Associate to another person authorized to access PHI at the same Covered Entity or Business Associate, or organized health care arrangement in which the Covered Entity participates, 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.
- c. A disclosure of PHI where a Covered Entity or Business Associate 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.*** “Business Associate” shall mean [**NAME OF BUSINESS ASSOCIATE**].
- 1.3 ***Covered Entity.*** “Covered Entity” shall mean the [**NAME OF COVERED ENTITY**].
- 1.4 ***Designated Record Set.*** “Designated Record Set” means “Designated Record Set” as defined in 45 C.F.R. § 164.501.
- 1.5 ***Electronic Health Record.*** “Electronic Health Record” shall mean an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.
- 1.6 ***Electronic Protected Health Information.*** “Electronic Protected Health Information” shall mean Protected Health Information that is transmitted or maintained in electronic format or by electronic media.
- 1.7 ***Individual.*** “Individual” shall have the same meaning as the term “Individual” in 45 C.F.R. § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
- 1.8 ***Privacy Rule.*** “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. parts § 160 and § 164, subparts A and E.
- 1.9 ***Protected Health Information (PHI).*** “Protected Health Information” (PHI) shall have the same meaning as the term “Protected Health Information” in 45 C.F.R. § 164.501, limited to the information received by Business Associate from, or on behalf of, Covered Entity.
- 1.10 ***Secretary.*** “Secretary” shall mean the Secretary of the Department of Health and Human Services or his/her designee.

- 1.11 *Security Incident.*** “Security Incident” shall have the same meaning as the term “Security Incident” in 45 C.F.R. § 164.304.
- 1.12 *Security Rule.*** “Security Rule” shall mean the Standards for Security of Electronic Protected Health Information at 45 C.F.R. § 160 and § 164, subparts A and C.
- 1.13 *Unsecured Protected Health Information or Unsecured PHI.*** “Unsecured PHI” shall mean protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of the HITECH Act on the HHS website.
- 1.14 *HITECH.*** “HITECH” shall mean the Health Information for Economic and Clinical Health Act, Subtitle D-Privacy (§§ 13400-13424) enacted as part of the America Recovery and Reinvestment Act of 2009.

Section 2

Obligations and Activities of Business Associate

Business Associate agrees to the following:

- 2.1 *Not to Use or Disclose PHI Unless Permitted.*** Business Associate agrees not to use, or further disclose, PHI other than as permitted or required by the Agreement or as required or allowed by law.
- 2.2 *Use Safeguards.*** Business Associate agrees to use reasonable safeguards to prevent use or disclosure of the PHI other than as allowed by this Agreement or as otherwise required or allowed by law. Business Associate will implement administrative, physical, technical and monitoring safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any Electronic Protected Health Information Business Associate creates, receives, maintains or transmits in accordance with HIPAA and HITECH rules and standards on behalf of Covered Entity.
- 2.3 *Mitigation of Harmful Effects.*** Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement
- 2.4 *Report Inappropriate Disclosures of PHI.*** Business Associate agrees to report to Covered Entity, including those occurrences reported to Business Associate by its subcontractors or agents, a discovery of Breach or any use or disclosure of the PHI not permitted or required by this Agreement within a reasonable period of time after becoming aware of such use or disclosure and not to exceed sixty (60) days. Business Associate also agrees to report to Covered Entity any Security Incident related to Electronic Protected Health Information of which Business Associate becomes aware.
- 2.5 *Report Breach of Unsecured PHI.*** In the case of a Breach of Unsecured PHI, Business Associate shall immediately notify Covered Entity as required under HITECH § 13402, 45 CFR § 164.410.

- 2.6 Compliance of Agents.** Business Associate agrees to require any agents, including subcontractors, to agree to the same restrictions and conditions that apply to Business Associate through this Agreement provided that such agents perform a service that the Business Associate agreed to perform for, or on behalf of, the Covered Entity under the Insurance Policy and, to whom the Business Associate provides PHI. Business Associate also agrees to ensure that any agent, including a subcontractor, to whom it provides Electronic Protected Health Information agrees to implement reasonable and appropriate safeguards to protect it.
- 2.7 Access.** To the extent the Business Associate maintains the Designated Record Set, Business Associate agrees to provide access to PHI in the original Designated Record Set, during normal business hours, provided the Covered Entity delivers prior written notice to the Business Associate, at least five business days in advance, requesting such access but only to the extent required by 45 C.F.R. § 164.524.
- 2.8 Amendments.** To the extent the Business Associate maintains the Designated Record Set, Business Associate agrees to incorporate any amendment(s) to PHI in the original Designated Record Set that the Covered Entity directs, pursuant to 45 C.F.R. § 164.526.
- 2.9 Disclosure of Practices, Books, and Records.** Unless otherwise protected from discovery or disclosure by law or unless otherwise prohibited from discovery or disclosure by law, Business Associate agrees to make internal practices, books, and records available to the Covered Entity or to the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule, or the Security Rule, but only to the extent such access is related to the use and disclosure of PHI received from the Covered Entity, or created or received by Business Associate on behalf of Covered Entity. Business Associate shall have a reasonable time within which to comply with such requests and, in no case shall access be required in less than five business days after the Business Associate's receipt of such request.
- 2.10 Accounting.** Business Associate agrees to maintain sufficient documentation to allow it to provide to Covered Entity a list of any disclosures of PHI by the Business Associate or its agents so as to allow the Covered Entity, or Business Associate on its behalf to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528 and 13405 (c)(3)
- 2.11 Release of Documentation of Disclosures.** Business Associate agrees to provide to Covered Entity, or as directed by Covered Entity to Individual, information collected in accordance with Section 2.9 of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. Business Associate shall have a reasonable time within which to comply with such requests and, in no case shall access be required in less than five business days after the Business Associate's receipt of such request.

Section 3
Permitted Uses and Disclosures by Business Associates

- 3.1. *Use of PHI for Specified Purposes.*** Under the business relationship, the Business Associate provides the Covered Entity with products and/or services, hereinafter “Services” that involve the use and disclosure of PHI as defined by the Privacy Regulations. These Services may include, among others, [***DESCRIPTION***], and other functions necessary to perform these Services. Except as otherwise specified herein, the Business Associate may make any uses of PHI necessary to perform its obligations under this Agreement. Moreover, the Business Associate may disclose PHI for the purposes authorized by this Agreement: (i) to its employees, subcontractors, and agents, in accordance with paragraphs Section 3.2 through 3.4 of this Section below; or (ii) as otherwise permitted by the terms of this Agreement. All other uses not authorized by this Agreement are prohibited..
- 3.2. *Use of PHI for Business Associate Management and Administration.*** Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
- 3.3. *Disclosure Required by Law or With Reasonable Assurances.*** Business Associate may disclose PHI for the proper management and administration of the Business Associate and to carry out its legal responsibilities, provided that disclosures are permitted by law, or provided that the Business Associate obtains the following reasonable assurances from the person or entity to whom the PHI is disclosed: 1) the PHI will remain confidential; 2) the PHI will be used or further disclosed only as required by law or for the purposes for which it was disclosed; and, 3) the person or entity will notify the Business Associate of any instances of which the person or entity is aware in which the confidentiality of the information has been breached.
- 3.4. *Data Aggregation Services.*** Business Associate may use PHI to provide data aggregation services to Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).

Section 4
Impermissible Requests by Covered Entity

- 4.1** Business Associate understands that the Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule if done by Covered Entity, except that, Business Associate may use or disclose PHI for data aggregation or management and administrative activities of Business Associate as is otherwise permitted by this Agreement.

Section 5
Term and Termination

- 5.1. *Term.*** The Term of this Agreement shall be effective as [***INSERT EFFECTIVE DATE***] between the Business Associate and the Covered Entity and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or, if it is not feasible to

destroy PHI, protections are extended to such information, in accordance with the termination provisions in this section.

- 5.2. *Termination for Cause.*** Upon Covered Entity's knowledge of a material breach by Business Associate of this Agreement, Covered Entity shall provide an opportunity for Business Associate to cure the breach or end the violation. Covered Entity may terminate this Agreement, and Business Associate agrees to such immediate termination, if Business Associate has breached a material term of this Agreement and cure is not possible.
- 5.3. *Effect of Termination.*** Upon termination of the Insurance Policy, the protections of this Agreement will remain in force and Business Associate shall make no further uses and disclosures of PHI except for the proper management and administration of its business or to carry out its legal responsibilities or as required by law.

Section 6

Miscellaneous Provisions

- 6.1. *Regulatory References.*** A reference in this Agreement to a section in the Privacy Rule or the Security Rule means the Section in effect or as amended, and for which compliance is required.
- 6.2. *Amendment.*** The Business Associate agrees to take such action as is necessary to amend this Agreement from time to time as is necessary, as determined by the Business Associate, for compliance with the requirements of the Privacy Rule, the Security Rule and the Health Insurance Portability and Accountability Act, Public Law 104-191 as determined by the Business Associate.
- 6.3. *Survival.*** The rights and obligations of Business Associate under this Agreement shall survive the termination of this Agreement and the termination of the Insurance Policy.
- 6.4. *Interpretation.*** Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy and Security Rules.
- 6.5. *Notices.*** All notices or communications required or permitted pursuant to the terms of this Agreement shall be in writing. All such notices will be deemed given upon delivery by service or in person, on the third business day after deposit with the U.S. Postal Service, or on the first business day after sending by facsimile or email. The Business Associate may, at its discretion, post this Agreement and any Amendments to this Agreement on its website for the Covered Entity to read and download, instead of mailing or otherwise delivering a copy of this Agreement or Amendments to the Covered Entity.
- 6.6. *Agreement in Effect.*** This Agreement supersedes all previous Business Associate Agreements by and between Business Associate and the Covered Entity.

[NAME OF BUSINESS ASSOCIATE]

Signature: _____

By: _____

Title: _____

[NAME OF COVERED ENTITY

Signature: _____

By: _____

Title: _____