**BUSINESS ASSOCIATE AGREEMENT**

 This **BUSINESS ASSOCIATE AGREEMENT** (“Agreement”) is entered into by and between **[INSERT NAME OF COVERED ENTITY]** (“Covered Entity”) and **CHALLENGERUNNER, LLC** (“Business Associate”) on this \_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_. This Agreement between Covered Entity and Business Associate outlines the terms of service for the secure and appropriate receipt, processing, disclosure, storage, removal and elimination of data classified as Protected Health Information, and for the implementation of appropriate safeguards to protect the confidentiality, integrity and availability of Electronic Protected Health Information.

**R E C I T A L S**

A. Covered Entity and Business Associate are entering into or have previously entered into a certain Services Agreement dated of even date herewith (“Services Agreement”).

B. Covered Entity and Business Associate have mutual obligations under the Services Agreement that necessitate the Business Associate performing functions or activities that will involve the use or disclosure of Covered Entity’s Protected Health Information as that term is defined by HIPAA.

C. This Agreement is intended to permit Covered Entity and Business Associate to access, use, disclose and exchange Protected Health Information in a manner which complies with HIPAA, as defined below.

**A G R E E M E N T**

**NOW, THEREFORE**, in consideration of the foregoing, the agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties, Covered Entity and Business Associate agree as follows:

#  – Definitions

 Terms used but not otherwise defined in this Agreement shall have the meanings given to them under HIPAA. To the extent a term is defined in both this Agreement and HIPAA, the definition given such term under HIPAA shall govern.

## **Breach**. “Breach” means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of the Standards for Privacy of Individually Identifiable Health Information (45. C.F.R. part 164) which compromises the security or privacy of the Protected Health Information.

## **Breach Notification Rule**. “Breach Notification Rule” means Notification in the Case of Breach of Unsecured Protected Health Information at 45 C.F.R. part 164, subpart D.

## **Designated Record Set**. “Designated Record Set” means a group of records maintained by or for a covered entity that is: (i) the medical records and billing records about individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for the covered entity to make decisions about individuals. For such purposes, the term “record” means “any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.”

## **Electronic Protected Health Information** or **EPHI**. “Electronic Protected Health Information” or “EPHI” means “individually identifiable health information (i) transmitted by electronic media; or (ii) maintained in electronic media,” limited to the information created, received, maintained or transmitted by Covered Entity from, to or on behalf of Business Associate.

## **Enforcement Rule.** “Enforcement Rule” means the enforcement standards located at 45 C.F.R. part 160, subparts C, D, and E.

## **HIPAA**. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and all corresponding regulations as may be amended from time, which includes but is not limited to the Privacy Rule, the Security Rule, the Breach Notification Rule and the Enforcement Rule.

## **Individual**. “Individual” means the person who is the subject of protected health information, and includes a person who qualifies as a personal representative in accordance with 45 C.F.R. 164.502(g).

## **Law Enforcement Official**. “Law Enforcement Official” means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to: (i) investigate or conduct an official inquiry into a potential violation of law; or (ii) prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

## **Privacy Rule**. “Privacy Rule” means the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. parts 160 and 164, subparts A and E.

## **Protected Health Information** or **PHI**. “Protected Health Information” or “PHI” means individually identifiable health information: (i) transmitted by electronic media; (ii) maintained in electronic media; or (iii) transmitted or maintained in any other form or medium,” limited to the information created, received, maintained or transmitted by Covered Entity from, or on behalf of Business Associate.

## **Required by Law**. “Required by Law” means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by Law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

## **Secretary**. “Secretary” means the Secretary of the Department of Health and Human Services or his designee.

## **Security Incident**. “Security Incident” means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

## **Security Rule**. “Security Rule” means the Security Standards for the Protection of Electronic Protected Health Information at 45 C.F.R. parts 160 and 164, subpart C.

#  – Obligations and Activities of Business Associate

 With regard to its use and disclosure of PHI, Business Associate agrees:

## to use or disclose PHI only if such use or disclosure is in compliance with each applicable requirement of 45 C.F.R. 164.504(e).

## to not use or disclose PHI other than as permitted or required by this Agreement or as Required by Law.

## to use appropriate safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement including the implementation of all requirements of the HIPAA Security Rule with respect to EPHI.

## to implement administrative, physical and technical safeguards in compliance with the Security Rule requirements at 45 C.F.R. sections 164.308, 164.310 and 164.312 that will protect the confidentiality, integrity and availability of the EPHI that Business Associate creates, receives, maintains or transmits on behalf of Covered Entity.

## 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.

## to the extent the Business Associate is to carry out the Covered Entity’s obligations under the Privacy Rule, the Business Associate shall comply with the Privacy Rule’s requirements that apply to the Covered Entity in the performance of such obligation.

## to require that any agent of Business Associate, including a subcontractor, to whom Business Associate provides PHI agrees, in writing, to restrictions and conditions with respect to such PHI as least as restrictive as those that apply through this Agreement to Business Associate with respect to such PHI.

## to provide access, at the request of Covered Entity and within fifteen (15) days of such request, to PHI in a Designated Record Set, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 C.F.R. 164.524. If an Individual makes a request for access to PHI directly to Business Associate, Business Associate shall notify Covered Entity of the request within five (5) business days of such request. Business Associate acknowledges that Individuals have the right to obtain access to their PHI in an electronic format, and Business Associate will provide PHI maintained in a Designated Record Set in an electronic format requested, if such format is readily producible, or in another readable electronic format as may be agreed to by the Individual.

## to make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 C.F.R. 164.526 at the request of Covered Entity, within fifteen (15) days of receiving such request. If an Individual makes a request for an amendment to PHI directly to Business Associate, Business Associate shall notify Covered Entity of the request within five (5) business days of such request.

## to make Business Associate’s internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity available to the Secretary, within fifteen (15) days or in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity’s compliance with the Privacy Rule.

## to document such disclosures of PHI and information related to such disclosures as would be required to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. 164.528. At a minimum, the following information regarding the disclosure will be documented: (i) the date of the disclosure; (ii) the name of the entity or person who received the Protected Health Information, and the address of such entity or person; (iii) a brief description of the Protected Health Information disclosed; (iv) a brief statement regarding the purpose and an explanation of the basis of such disclosure; and (v) the names of Individuals whose Protected Health Information was disclosed.

## to provide to Covered Entity, within thirty (30) days of receiving a request by the Covered Entity or an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. 164.528, information collected in accordance with Section 2.11 of this Agreement, to permit Covered Entity to respond to such a request; and if such a request is to Business Associate by an Individual to provide notice of the request to Covered Entity within ten (10) days of receiving the request.

## to not directly or indirectly receive remuneration in exchange for any PHI unless one of the following applies:

### Covered Entity has obtained an authorization from such Individual (and provided a copy of the authorization to the Individual) that meets the requirements of 45 C.F.R. 164.508(c) which is signed and dated by the Individual and contains, at a minimum, a statement that direct or indirect remuneration to Covered Entity or Business Associate from a third party is involved.

### The purpose of the exchange meets an exception detailed in 45 C.F.R. 164.502(a)(5)(ii)(B)(2).

#  – Permitted Uses and Disclosures by Business Associate

## **General Use and Disclosure Provision**. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified inthe Services Agreement, provided that such use or disclosure does not violate HIPAA, including its minimum necessary requirements.

## **Specific Use and Disclosure Provision**.

### Except as otherwise limited in this Agreement, 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.

### Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

### Business Associate may use or disclose PHI as Required by Law.

#  – Reporting Obligations of Business Associate

## Business Associate agrees to notify Covered Entity within forty-eight (48) hours following the discovery of any Breach.

## Business Associate agrees to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement of which it becomes aware.

## Business Associate agrees to report to Covered Entity any Security Incident of which it becomes aware.

## Business Associate agrees to notify Covered Entity following the discovery of any Breach of unsecured PHI as required by 45 C.F.R. 164.410.

## Business Associate agrees to fully cooperate with any investigation or risk assessment of a reported Breach performed by Covered Entity.

## A Breach is considered discovered by Business Associate as of the first day on which the unauthorized acquisition, access, use or disclosure of the PHI was known, or by exercising reasonable diligence, would have been known to Business Associate or any employee, officer, or agent, as determined under the Federal common law of agency of Business Associate, other than the individual committing the Breach.

## The notice to Covered Entity shall include, to the extent such information is available at the time of notification;

### The identification of each Individual whose unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed during the Breach;

### A description of the types of unsecured PHI that have involved in the Breach (such as whether the Individuals’ full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved); and

### A brief description of what happened, including the date of the Breach, if known, and the date the Breach was discovered.

## Business Associate shall also provide Covered Entity with the following information in the notification to Covered Entity, or as it becomes available, but no later than thirty (30) days after the Breach is discovered:

### Any steps Individuals should take to protect themselves from potential harm that may result from the Breach;

### A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to the Individuals, and to protect against any further Breaches; and

### Contact procedures for Individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

## The notification described in this Section 4 shall be provided to Covered Entity’s Privacy Officer, or such other person as Covered Entity may designate from time to time.

## In the event that a Law Enforcement Official instructs Business Associate to delay notification to Covered Entity, Business Associate shall be permitted to do so; provided, however, that if a Law Enforcement Official’s instructions are oral, Business Associate may not delay notification to Covered Entity more than thirty (30) days from the date of the oral statement unless, during such thirty (30) day period, Business Associate receives a written statement from a Law Enforcement Official which specifies a longer time period to delay notification.

#  – Obligations of Covered Entity

## **Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**.

### Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 C.F.R. 164.520, to the extent that such limitation may affect Business Associate’s use or disclosure of PHI.

### Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI, to the extent that such changes may affect Business Associate’s use or disclosure of Protected Health Information.

### Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 C.F.R. 164.522, to the extent that such restriction may affect Business Associate’s use or disclosure of PHI.

## **Permissible Requests by Covered Entity**. Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that causes Business Associate to violate the Privacy Rule.

#  – Term and Termination

## **Term**. This Agreement shall become effective on the date the Services Agreement becomes effective, or in the event the parties have already entered into a Services Agreement, this Agreement shall be in effect as of the date first set forth above, and shall terminate when the Services Agreement terminates, unless otherwise terminated in accordance therein.

## **Continuation of Agreement**. This Agreement supersedes any prior Business Associate Agreement between Covered Entity and Business Associate. This Agreement shall continue after any new Services Agreement is entered into between Covered Entity and Business Associate except to the extent that such other agreement includes business associate agreement provisions or specifically states that it supersedes this Agreement.

## **Termination for Cause**. Upon a party’s knowledge of a material breach by the other party, the non-breaching party shall either:

### Provide an opportunity for the breaching party to cure the breach or end the violation, and terminate this Agreement if the breaching party does not cure the breach or end the violation within the reasonable time specified by the non-breaching party; or

### Immediately terminate this Agreement if the breaching party has breached a material term of this Agreement and cure is not possible.

## **Effect of Termination**.

### Except as provided in paragraph (b) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.

### In the event that Business Associate determines that returning or destroying the PHI is infeasible, for example, because such information must be retained for compliance with applicable laws, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon notification that return or destruction of PHI is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

### This Section 6.4 shall survive termination of this Agreement and the Services Agreement.

#  – Miscellaneous

## **Independent Contractor**. Covered Entity and Business Associate expressly acknowledge and agree that Business Associate is an “independent contractor” and shall not for any purpose be deemed to be an agent (as determined in accordance with the federal common law of agency), employee, servant, partner or joint venturer of Covered Entity.

## **Regulatory References**. A reference in this Agreement to a section in the Privacy Rule, the Security Rule, the Breach Notification Rule, the Enforcement Rule or HIPAA means the relevant section as in effect or as amended.

## **Amendment**. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary to comply with the requirements of HIPAA, and any rules and regulations promulgated thereunder. In the event that the parties are unable to agree to such amendment, the parties may terminate this Agreement in accordance with Section 6.

## **State Law.** Where any provision of applicable state law is more stringent or otherwise constitutes a basis upon which HIPAA is preempted, such state law controls and the parties agree to comply fully therewith.

## **Assignment**. Neither this Agreement nor any rights or obligations hereunder may be assigned, in whole or in part, without the prior written consent of the other party.

## **No Third Party Beneficiaries**. This Agreement is effective only in regards to the rights and obligations of Covered Entity and Business Associate. Covered Entity and Business Associate expressly do not intend this Agreement to create any independent rights in any third party or to make any third party a beneficiary of this Agreement.

## **Survival**. The respective rights and obligations of Business Associate under Section 6.4 of this Agreement shall survive the expiration or termination of this Agreement and the Services Agreement, regardless of the cause of such termination

## **Interpretation**. Any ambiguity in this Agreement shall be resolved to permit compliance with HIPAA and any rules and regulations thereunder, as they may become available or effective.

**[Signature Page to Follow]**

 **IN WITNESS WHEREOF**, the parties have caused this Business Associate Agreement to be executed in their respective names or by their respective officers, thereunto duly authorized, as of the date set forth in the preamble hereto.

 **“COVERED ENTITY”**

 **[INSERT NAME OF COVERED ENTITY]**

By:

Name:

Title:

 **“BUSINESS ASSOCIATE”**

 **CHALLENGERUNNER, LLC**

By:

Name:

Title: