

## BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT ("BAA") is entered into as of \_\_\_\_\_ ("Effective Date") by and between Azalea Health Innovations, Inc., a C-Corporation company organized under the laws of the state of Delaware, with offices at 5871 Glenridge Drive, Suite 480, Atlanta, GA 30328 ("Covered Entity" or "Azalea Health"), and \_\_\_\_\_, a \_\_\_\_\_ company organized under the laws of \_\_\_\_\_ with offices at \_\_\_\_\_ ("Business Associate" or "\_\_\_\_\_"). The Business Associate and Covered Entity referred to as "the Parties" in this Agreement.

### RECITALS:

Covered Entity provides services that pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requires Covered Entity to restrict the uses and disclosures of Protected Health Information, as defined by HIPAA, in accordance with the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Part 164, Subparts A and E as amended from time to time (the "Privacy Rule"), and Subparts A and C as amended from time to time (the "Security Rule") under HIPAA, which was amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), as Title XIII Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub.L. 111- 5). Pursuant to the services agreement between Covered Entity and Business Associate, Business Associate is receiving access to use or disclose Protected Health Information for the purposes of providing services on behalf of Covered Entity. Thus, pursuant to the state and federal regulations, Business Associate is required to comply with the state privacy and security laws that are not preempted by HIPAA, HIPAA Privacy and Security Rules, the HIPAA requirements as amended by the HITECH Act and the HITECH Act and its accompanying and implementing regulations.

**NOW, THEREFORE,** the parties, in consideration of the mutual agreements herein contained and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, do hereby agree as follows:

**1. Definitions.** Unless otherwise provided in this Agreement, capitalized terms shall have the same meanings as set forth in the Standards for Privacy or Security of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A and E. a.

- a. "**Breach**" shall have the same meaning as the term "breach" given in 45

C.F.R. § 164.402 and shall include the unauthorized acquisition, access, use or disclosure of Protected Health Information that compromises the security or privacy of such information.

- b. **"Business Associate Agreement(s)"** shall mean any agreement between Business Associate and a Covered Entity, which is intended to comply with 45 C.F.R. 164.502(e) and 45 C.F.R. 164.504(c), as amended.
- c. **"Designated Record Set"** shall mean 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 covered entity, (ii) enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a Health Plan, and (iii) used, in whole or in part, by or for covered entity to make decisions about Individuals. For the purposes of this paragraph, the term **"Record"** means any items, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for covered entity.
- d. **"Electronic Protected Health Information"** or "Electronic PHI" shall have the meaning in 45 C.F.R. 160.103.
- e. **"HHS"** shall mean the United States Department of Health and Human Services.
- f. **"Individually Identifiable Health Information"** shall mean information that is a subset of health information, including demographic information, that is collected from an Individual and (1) is created or received by a covered entity or an employer; (2) relates to the past, present or future physical or mental health or condition of an Individual, the provision of healthcare to an Individual, or the past, present, or future payment for the provision of healthcare to an Individual; and (3) identifies the Individual or there is a reasonable basis to believe the information can be used to identify the Individual.
- g. **"Individual(s)"** shall have the same meaning as the term "individual" in 45 C.F.R. 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. 164.502(g).
- h. **"Information System"** means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications and people.

- i. **"Privacy Rules"** shall mean the Standards for Privacy of Individually Identifiable Health Information found at 45 C.F.R. §§ 160 and 164, subparts A and E in effect or as amended, and with which compliance is required.
- j. **"Protected Health Information ("PHI")"** shall have the same meaning as the term "protected health information" in 45 C.F.R. 160.103.
- k. **"Required by Law"** shall have the same meaning as the term "required by law" in 45 C.F.R. 164.103 and 45 C.F.R. 164.512(a).
- l. **"Secretary"** shall mean the Secretary of HHS or his/her designee.
- m. **"Security Incident"** shall have the meaning as the term "Security Incident" in 45 C.F.R. 164.304, which means the attempted or successful unauthorized access.
- n. **"Security Rule"** shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A , C and E, in effect or as amended, and with which compliance is required.
- o. **"Unsecured PHI"** shall mean Protected Health Information that is not secured through the use of a technology or methodology specified by the Secretary in guidance or as otherwise defined in 45 C.F.R. 164.402.

## 2. **Obligations and Activities of Business Associate.**

- a. Permitted Uses. Business Associate agrees to use or disclose PHI in accordance with the terms of this Agreement or as Required by Law.
- b. Appropriate Safeguards. Business Associate agrees to implement appropriate and reasonable administrative, technical and physical safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement.
- c. Mitigation. 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.
- c. Mitigation. 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.

d. Report Breach.

1) Business Associate agrees to report to Covered Entity any use or disclosure of the PHI not provided for by this Agreement, including any Security Incident of which it becomes aware. Upon discovery of a breach of the security of PHI or a Security Incident, Business Associate shall notify Covered Entity within ten (10) business days. Notice should include the identification of each individual whose PHI has been or is reasonably believed to have been breached, the PHI that was believed to be disclosed, the mitigation actions taken by the Business Associate to prevent future breaches and any other information necessary for the Covered Entity to comply with the notification requirements promulgated by HIPAA and HITECH.

2) Business Associate agrees to notify Covered Entity of any Breach of Unsecured Protected Health Information as required at 45 CFR 164.410, within ten (10) business days of the date Business Associate learns of the Breach. Business Associate shall provide such information to Covered Entity as required by the Breach Notification Standards set forth in the HITECH Act. Business Associate shall cooperate and assist Covered Entity in making the notification to third parties required by law in the event of a Breach due to Business Associate. In addition, Business Associate shall reimburse Covered Entity for any reasonable expenses Covered Entity incurs in mitigating harm to those Individuals.

e. Agents and Subcontractors. Business Associate agrees to notify Subcontractors of the Business Associate, to whom it provides PHI received from, or created or received by Business Associate on behalf of Covered Entity of the restrictions and conditions that apply through this Agreement to Business Associate with respect to such information, including the safeguards contained in this Agreement and to require Subcontractor to sign an agreement with the similar or same restrictions and obligations.

Any subcontractor or third-party service provider providing artificial intelligence, machine learning, or automated data processing services that creates, receives, maintains, or transmits PHI on behalf of the Business Associate must enter into a Business Associate Agreement and comply with the same restrictions and safeguards required under this Agreement.

f. Access to Protected Health Information. Business Associate agrees to provide access to PHI maintained in a Designated Record Set, within twenty (20) days upon receipt of the request of Covered Entity, to ensure Covered Entity has reasonable time to comply with the requirements under 45 C.F.R. 164.524. g. Amendment of Protected Health Information. Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 C.F.R. 164.526, at the request of Covered Entity or an Individual, in the time required by HIPAA Rules.

h. Governmental Access to Records. Business Associate agrees to make its internal practices, books and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received for Covered Entity, available to the Secretary, for the purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

i. Accounting of Disclosures. Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity, to respond to an accounting of disclosures of PHI under 45 CFR §164.528. Business Associate agrees to provide Covered Entity, or an Individual, an accounting of the disclosures required by 45 C.F.R. §164.528, within twenty (20) days upon receipt of the request and in the manner directed by the accounting requirements established by HIPAA. Business Associate shall document the following information and maintain such documentation for a minimum of six (6) years for paper records and three (3) years for electronic health records: (1) the name and address of the entity to whom the Protected Health Information was disclosed; (2) the date of the disclosure; (3) a brief description of the Protected Health Information disclosed; (4) a brief description of the purpose for the disclosure; and (5) any other information related to such disclosures as required to enable Covered Entity to comply with 45 C.F.R. § 164.528.

j. Security Standards. Business Associate shall 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 Agreement.

k. Agent Protection of Electronic PHI. In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), ensure that any Subcontractors that create, receive, maintain, or transmit protected health information on behalf

of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information

l. Minimum Necessary. Business Associate acknowledges that it shall limit the use, disclosure or request of PHI to perform or fulfill a specific function required or permitted hereunder to the Minimum Necessary, as defined by HIPAA Standards and relevant guidance, to accomplish the purpose of such use, disclosure or request.

m. Standard Transactions. If Business Associate conducts any Standard Transactions on behalf of Covered Entity, Business Associate shall comply with the applicable requirements of 45 C.F.R. Part 162.

n. Restrictions on Use and Disclosure. Business Associate shall comply with the requests for restrictions on use or disclosure to health plans for payment or health care purposes when the provider has been paid out of pocket in full.

o. Sale of PHI. Business Associate shall not receive remuneration in exchange for the disclosure of Protected Health Information without authorization unless the disclosure satisfies an exception to the HIPAA Rules as defined at 45 C.F.R. 164.502(a)(5)(ii).

p. Marketing. Business associate shall not engage in the use or disclosure of Protected Health Information for certain communications that fall within the definition of marketing under 45 C.F.R. §164.501 unless a valid Authorization is obtained;

q. Security Safeguards. Business Associate shall comply with each of the Standards and Implementation Specifications of 45 C.F.R. §164.308 (Administrative Safeguards), 45 C.F.R. §164.310 (Physical Safeguards), 45 C.F.R. §164.312 (Technical Safeguards) and 45 C.F.R. §164.316 (Policies and Procedures and Documentation Requirements).

### **3. Permitted Uses and Disclosures by Business Associate**

a. Permitted Uses and Disclosures under this Agreement:

- 1) Business associate may use or disclose protected health information as required by law.
- 2) Business associate may only use or disclose protected health

information as necessary to perform the services set forth in Service Agreement.

3) Business Associate may utilize automated processing, machine learning, or artificial intelligence technologies to process Protected Health Information solely as necessary to perform the services described in the Service Agreement, provided such processing complies with all applicable HIPAA Privacy and Security Rule requirements and the safeguards described in this Agreement.

4) Business Associate shall not use Protected Health Information to train, develop, or improve generalized artificial intelligence or machine learning models that are not exclusively used for providing services to Covered Entity, unless such information has been de-identified in accordance with 45 CFR 164.514.

b. Management and Administration. Except as otherwise limited in this Agreement or through the agreement between Business Associate and Covered Entity, 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. In the event of disclosure to a third party for purposes described herein, Business Associate shall obtain satisfactory assurances from the receiving party that it shall maintain the privacy and security of the information as required by law, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

c. Aggregation Services. Business associate may provide data aggregation services relating to the health care operations of the covered entity.

d. De-identification. Business Associate is authorized to use protected health information to de-identify the information in accordance with 45 CFR 164.514(a)- (c) and to use and disclose such de-identified information.

#### **4. Obligations of Covered Entity**

a. Revocation of Consent. Covered Entity shall notify Business Associate in writing of any changes in, or revocation of, permission by Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

b. Restrictions on Use of Protected Health Information. Covered Entity shall notify Business Associate in writing 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.

c. Notice of Privacy Rights. Covered Entity shall provide Business Associate with notice of any restrictions on the use or disclosure of PHI provided in the Covered Entity Notice of Privacy Rights.

## **5. Term and Termination**

a. Term. The Term of this Agreement shall be effective on the effective date of the underlying agreement, 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 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 in this Section.

b. Termination For Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

1) Provide an opportunity for Business Associate to cure the breach within thirty (30) days; or

2) Immediately terminate the Agreement if Business Associate has breached a material term of the Agreement and cure is not possible; or

3) If cure or immediate termination is not possible, Covered Entity shall notify Business Associate of its intent to report the material breach to the Secretary of HHS.

c. Effect of Termination. Except as provided below, upon termination or expiration 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. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of 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.

**6. Entire Agreement.** This Agreement supersedes any and all other agreements, whether oral or in writing, between the Parties with respect to PHI, and this Agreement contains all of the covenants and agreements between the Parties with respect to PHI in any manner whatsoever. Each Party to this Agreement acknowledges that no representations, inducements, promises, or agreements, orally or otherwise, have been made by any Party, or anyone acting on behalf of any Party, that are not embodied in this Agreement, and that no other agreement, statement, or promise not contained in this Agreement shall be valid or binding.

**7. Modification.** No change or modification of this Agreement shall be valid or binding unless the same is in writing and signed by each of the Parties hereto.

**8. Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the State of Georgia.

**9. No Third Party Beneficiaries.** Nothing express or implied in this Agreement or in the Service Agreement 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.

**10. Amendment.** This Agreement shall automatically be deemed amended and any conflicting terms shall be superseded by new regulations in order to support compliance with the HIPAA Privacy and Security Rule as amended through the regulatory process. Business Associate and Covered Entity agree to comply with the applicable laws and regulations. Any other amendments or modifications shall only be amended through a written amendment by both parties.

**11. Regulatory References.** A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

**12. Interpretation.** Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

**IN WITNESS WHEREOF**, the parties have hereunto set their hands as of the day and year first above written.

BUSINESS ASSOCIATE

COVERED ENTITY

\_\_\_\_\_  
("Licensee", "You", "Your")

Azalea Health Innovations, Inc.

by

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