

Darmiyan, Inc.

HIPAA Business Associate Agreement

1. PREAMBLE AND DEFINITIONS.

1.1 Pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended (“**HIPAA**”), the undersigned covered entity (“**Covered Entity**”), and Darmiyan, Inc., a Delaware corporation, or any of its corporate affiliates (“**Business Associate**”), enter into this Business Associate Agreement (“**BAA**”) as of the signature date of the Covered Entity (the “**Effective Date**”) that addresses HIPAA requirements as set forth at 45 C.F.R. Part 160 and Part 164 (“**HIPAA Rules**”). A reference in this BAA to a section in the HIPAA Rules means the section as in current effect or as subsequently amended, as applicable.

1.2 This BAA is intended to ensure that Business Associate will establish and implement appropriate safeguards for the Protected Health Information (“**PHI**”) (as defined under the HIPAA Rules) that Business Associate may receive, create, maintain, use, or disclose in connection with the functions, activities, and services that Business Associate performs for Covered Entity.

1.3 Pursuant to changes required under the Health Information Technology for Economic and Clinical Health Act of 2009 (the “**HITECH Act**”) and under the American Recovery and Reinvestment Act of 2009 (“**ARRA**”), this BAA also reflects federal breach notification requirements imposed on Business Associate when “Unsecured PHI” (as defined under the HIPAA Rules) is acquired by an unauthorized party, and the expanded privacy and security provisions imposed on business associates.

1.4 Unless the context clearly indicates otherwise, the following terms in this BAA shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, disclosure, Electronic Media, Electronic Protected Health Information (“**ePHI**”), Health Care Operations, individual, Minimum Necessary, Notice of Privacy Practices, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured PHI, and use.

1.5 A reference in this BAA to the Privacy Rule means the Privacy Rule, in conformity with the regulations at 45 C.F.R. Parts 160-164 (the “**Privacy Rule**”) as interpreted under applicable regulations and guidance of general application published by HHS, including all amendments thereto for which compliance is required, as amended by the HITECH Act, ARRA, and the HIPAA Rules.

2. GENERAL OBLIGATIONS OF BUSINESS ASSOCIATE.

2.1 Business Associate agrees not to use or disclose PHI, other than as permitted or required by this BAA or as Required By Law, or if such use or disclosure does not otherwise cause a Breach of Unsecured PHI.

2.2 Business Associate agrees to use appropriate safeguards, and comply with Subpart C of 45 C.F.R. Part 164 with respect to ePHI, to prevent use or disclosure of PHI other than as provided for by the BAA.

2.3 Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate as a result of a use or disclosure of PHI by Business Associate in violation of this BAA's requirements or that would otherwise cause a Breach of Unsecured PHI.

2.4 The Business Associate agrees to the following breach notification requirements:

(a) Business Associate agrees to report to Covered Entity any Breach of Unsecured PHI not provided for by the BAA of which it becomes aware within 10 calendar days of "discovery" within the meaning of the HITECH Act, as codified at 42 U.S.C. § 17932(c). Such notice shall include the identification of each individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, or disclosed in connection with such Breach.

(b) Business Associate shall provide any additional information reasonably requested by Covered Entity for purposes of investigating the Breach and any other available information that Covered Entity is required to include to the individual under 45 C.F.R. § 164.404(c) at the time of notification or promptly thereafter as information becomes available. Business Associate's notification of a Breach of Unsecured PHI under this Section shall comply in all respects with each applicable provision of Section 13400 of Subtitle D (Privacy) of ARRA, the HIPAA Rules, and related guidance issued by the Secretary or the delegate of the Secretary from time to time.

2.5 Business Associate agrees, in accordance with 45 C.F.R. §§ 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, to require that any Subcontractors that create, receive, maintain, or transmit PHI 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.

2.6 Business Associate agrees to make available PHI in a Designated Record Set to the Covered Entity as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.524.

(a) Business Associate agrees to comply with an individual's request to restrict the disclosure of their personal PHI in a manner consistent with 45 C.F.R. § 164.522, except where such use, disclosure, or request is required or permitted under applicable law.

(b) Business Associate agrees that when requesting, using, or disclosing PHI in accordance with 45 C.F.R. § 164.502(b)(1) that such request, use, or disclosure shall be to the minimum extent necessary, including the use of a "limited data set" as defined in 45 C.F.R. § 164.514(e)(2), to accomplish the intended purpose of such request, use, or disclosure, as interpreted under related guidance issued by the Secretary from time to time.

2.7 Business Associate agrees to make any amendments to PHI in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 C.F.R. § 164.526, or take other measures as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.526.

2.8 Business Associate agrees to maintain and make available the information required to provide an accounting of disclosures to the Covered Entity as necessary to satisfy Covered Entity's obligations under 45 C.F.R. § 164.528.

2.9 Business Associate agrees to make its internal practices, books, and records, including policies and procedures regarding PHI, relating to the use and disclosure of PHI and Breach of any Unsecured PHI received from Covered Entity, or created or received by the Business Associate on behalf of Covered

Entity, available to the Secretary for the purpose of Covered Entity or the Secretary determining compliance with the Privacy Rule.

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

2.11 Business Associate agrees to account for the following disclosures:

(a) Business Associate agrees to maintain and document disclosures of PHI and Breaches of Unsecured PHI and any information relating to the disclosure of PHI and Breach of Unsecured PHI in a manner as would be required for Covered Entity to respond to a request by an individual or the Secretary for an accounting of PHI disclosures and Breaches of Unsecured PHI.

(b) Business Associate agrees to provide to Covered Entity information collected in accordance with this Section 2.11, to permit Covered Entity to respond to a request by an individual or the Secretary for an accounting of PHI disclosures and Breaches of Unsecured PHI.

(c) Business Associate agrees to account for any disclosure of PHI used or maintained as an EHR (as defined in Section 5) in a manner consistent with 45 C.F.R. § 164.528 and related guidance issued by the Secretary from time to time; provided that an individual shall have the right to receive an accounting of disclosures of EHR by the Business Associate made on behalf of the Covered Entity only during the three years prior to the date on which the accounting is requested from Covered Entity.

2.12 Business Associate agrees to comply with the "Prohibition on Sale of Electronic Health Records or Protected Health Information," as provided in Section 13405(d) of Subtitle D (Privacy) of ARRA, and the "Conditions on Certain Contacts as Part of Health Care Operations," as provided in Section 13406 of Subtitle D (Privacy) of ARRA and related guidance issued by the Secretary from time to time.

2.13 Business Associate acknowledges that, effective on the Effective Date of this BAA, it shall be subject to the civil and criminal enforcement provisions set forth at 42 U.S.C. § 1320d-5 and 1320d-6, as amended.

3. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE.

3.1 General Uses and Disclosures. Business Associate agrees to receive, create, use, or disclose PHI only in a manner that is consistent with this BAA, the Privacy Rule or Security Rule (as defined in Section 5), or as necessary to perform the services set forth in any applicable agreement between Business Associate and Covered Entity, and only in connection with providing services to Covered Entity; provided that the use or disclosure would not violate the Privacy Rule, including 45 C.F.R. § 164.504(e), if the use or disclosure would be done by Covered Entity. For example, the use and disclosure of PHI will be permitted for "treatment, payment, and health care operations," in accordance with the Privacy Rule.

3.2 Business Associate may additionally use or disclose PHI as Required By Law, or for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.

3.3 Business Associate agrees to make uses and disclosures and requests for PHI consistent with Covered Entity's Minimum Necessary policies and procedures.

3.4 Business Associate may not use or disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by the Covered Entity, except for the specific uses and disclosures set for in Section 3.2.

4. OBLIGATIONS OF COVERED ENTITY.

4.1 Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy and Security Rule if done by Covered Entity, except as provided under Section 3 of this BAA.

5. COMPLIANCE WITH SECURITY RULE.

5.1 Business Associate shall comply with the HIPAA Security Rule, which shall mean the Standards for Security of Electronic Protected Health Information at 45 C.F.R. Part 160 and Subparts A and C of Part 164, as amended by ARRA and the HITECH Act. The term “**Electronic Health Record**” or “**EHR**” as used in this BAA 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.

5.2 In accordance with the Security Rule, Business Associate agrees to:

(a) Implement the administrative safeguards set forth at 45 C.F.R. § 164.308, the physical safeguards set forth at 45 C.F.R. § 164.310, the technical safeguards set forth at 45 C.F.R. § 164.312, and the policies and procedures set forth at 45 C.F.R. § 164.316, in each case to the extent required, to reasonably and appropriately protect the confidentiality, integrity, and availability of the ePHI that it creates, receives, maintains, or transmits on behalf of Covered Entity and as required by the Security Rule. Business Associate acknowledges that, effective on the Effective Date of this BAA, (a) the foregoing safeguards, policies, and procedures requirements shall apply to Business Associate in the same manner that such requirements apply to Covered Entity, and (b) Business Associate is subject to the civil and criminal enforcement provisions set forth at 42 U.S.C. § 1320d-5 and 1320d-6, as amended from time to time;

(b) Require that any agent, including a Subcontractor, to whom it provides such PHI agrees to implement reasonable and appropriate safeguards to protect the PHI; and

(c) Report to the Covered Entity any Security Incident of which it becomes aware.

6. TERM AND TERMINATION.

6.1 This BAA shall be in effect as of the signature date of the Covered Entity, and shall terminate on the earlier of the date that:

(a) Either party terminates for cause as authorized under Section 6.2.

(b) All of the PHI received from Covered Entity or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity. If it is not feasible to return or destroy PHI, protections are extended in accordance with Section 6.3.

6.2 Upon either party's knowledge of material breach by the other party, the non-breaching party shall provide an opportunity for the breaching party to cure the breach or end the violation; or terminate the BAA. If the breaching party does not cure the breach or end the violation within a reasonable timeframe

not to exceed 30 days from the notification of the breach, or if a material term of the BAA has been breached and a cure is not possible, the non-breaching party may terminate this BAA, upon written notice to the other party.

6.3 Upon termination of this BAA for any reason, the parties agree that:

(a) Business associate shall return to Covered Entity or, if agreed to by Covered Entity, destroy all PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. The PHI shall be returned in a format that is reasonably expected to preserve its accessibility and usability.

(b) Business Associate shall retain no copies of the PHI except to the extent necessary for proper management and administration of Business Associate or to carry out its legal responsibilities

7. MISCELLANEOUS.

7.1 The parties agree to take such action as is necessary to amend this BAA to comply with the requirements of the Privacy Rule, the Security Rule, HIPAA, ARRA, the HITECH Act, the HIPAA Rules, and any other applicable law.

7.2 The respective rights and obligations of Business Associate under Section 6 of this BAA shall survive the termination of this BAA.

7.3 This BAA shall be interpreted in the following manner:

(a) Any ambiguity shall be resolved in favor of a meaning that permits Covered Entity to comply with the HIPAA Rules.

(b) Any inconsistency between the BAA's provisions and the HIPAA Rules, including all amendments, as interpreted by the HHS, a court, or another regulatory agency with authority over the Parties, shall be interpreted according to the interpretation of the HHS, the court, or the regulatory agency.

(c) Any provision of this BAA that differs from those required by the HIPAA Rules, but is nonetheless permitted by the HIPAA Rules, shall be adhered to as stated in this BAA.

7.4 This BAA constitutes the entire agreement between the parties related to the subject matter of this BAA. This BAA supersedes all prior negotiations, discussions, representations, or proposals, whether oral or written. This BAA may not be modified unless done so in writing and signed by a duly authorized representative of both parties. If any provision of this BAA, or part thereof, is found to be invalid, the remaining provisions shall remain in effect.

7.5 This BAA will be binding on the successors and assigns of the Covered Entity and the Business Associate. However, this BAA may not be assigned, in whole or in part, without the written consent of the other party. Any attempted assignment in violation of this provision shall be null and void.

7.6 This BAA may be executed in two or more counterparts, each of which shall be deemed an original.

7.7 Except to the extent preempted by federal law, this BAA shall be governed by and construed in accordance with the laws of the state of California, U.S.A. Each of the Covered Entity and the Business

Associate agrees that any proceeding arising out of or relating to this BAA shall be brought exclusively in the federal or state courts located in San Francisco County, State of California, U.S.A., and each of the parties hereby submits to the exclusive jurisdiction of such courts for itself and with respect to its property, generally and unconditionally, for the purpose of any such proceeding.

IN WITNESS WHEREOF, the parties hereto have executed this BAA as of the date signed below by the Covered Entity.