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## **BUSINESS ASSOCIATE AGREEMENT**

This Business Associate Agreement ("Agreement") is by and between \_\_\_\_\_ ("Covered Entity"), an organization with its principal place of business at \_\_\_\_\_, and Otto Bock Healthcare, LP ("Business Associate"), with its principal place of business in Plymouth, MN and is effective as of \_\_\_\_\_ 201\_\_ ("Effective Date").

WHEREAS, \_\_\_\_\_ is a Covered Entity as defined in the regulation promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); and

WHEREAS, Covered Entity may disclose or make available to Business Associate and Business Associate may use, disclose, receive, transmit, maintain or create from or on behalf of Covered Entity, certain information in order to provide the services or perform the function for which Covered Entity has retained Business Associate; and

WHEREAS, the purpose of this Agreement is to satisfy the obligations of Covered Entity under HIPAA and to ensure the integrity and confidentiality of certain information that Business Associate uses, discloses, receives, transmits, maintains or creates on behalf of Covered Entity now and in the future,

NOW, THEREFORE, the Parties agree as follows:

**1. Definitions.** Terms used, but not otherwise defined in this Agreement, shall have the same meaning as those terms in the Privacy Rule and the Security Rule.

- a. **Business Associate.** "Business Associate" shall mean a person or entity that performs certain functions or activities that involve the use or disclosure of PHI on behalf of, or provides services to, a Covered Entity as defined in 45 CFR § 164.502 (e).
- b. **Covered Entity.** "Covered Entity" shall have the meaning given such terms in 45 CFR §160.103 to include a: (1) health plan; (2) healthcare clearinghouse; or (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by the subsection.
- c. **Individual.** "Individual" shall have the same meaning as the term "individual" in 45 CFR §160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
- d. **Privacy Rule.** "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.
- e. **Protected Health Information.** "Protected Health Information" (PHI) shall have the same meaning as the term "protected health information" in 45 CFR §160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.



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- f. **Required By Law.** "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR §164.103.
- g. **Secretary.** "Secretary" shall mean the Secretary of the Department of Health and Human Services or his or her designee.
- h. **Security Rule.** "Security Rule" shall mean the Standards for Security of Electronic PHI at 45 C.F.R. parts §160 and §164, subparts A and C.

## 2. **Scope and Interpretation**

The terms and conditions of this Agreement shall supplement and amend all present and future Agreements and relationships between the Parties, whether written, oral or implied ("Base Agreement" or collectively, "Base Agreements"), which provide for Business Associate's receipt, transmission, maintenance, creation, use and disclosure of PHI, in any form or medium, including electronic PHI in Business Associate's capacity as a Business Associate to Covered Entity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy and Security Rules. In the event of any inconsistency or conflict between Base Agreement (s) and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall control. Except as supplemented and/or amended, the terms of the Base Agreement (s) shall continue unchanged and shall apply with full force and effect to govern the matters addressed in the Base Agreement (s).

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

Business Associate agrees to:

- a. Not use or disclose PHI other than as permitted or required by this Agreement or as required by law.
- b. Use appropriate safeguards to prevent use or disclosure of the PHI other than as provided for by this Agreement. Business Associate agrees to implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any electronic PHI that Business Associate creates, receives, maintains or transmits on behalf of Covered Entity, as provided for in the Security Rule.
- c. 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 to Covered Entity any unauthorized use or disclosure of the PHI by Business Associate or its workforce or subcontractors within five (5) business days and the remedial action taken or proposed to be taken with respect to such use or disclosure and account for such disclosure. Business Associate is responsible for any and all costs related to notification of individuals or next of kin (if the Individual is deceased) of any security or privacy breach reported by Business Associate to Covered Entity.
- e. In the event of a breach of PHI, Business Associate understands that Business Associate is required by law to provide Covered Entity a report including individual name, contact information, nature/cause of breach, PHI breached, and the date or period of time during which the breach occurred. Business Associate understands



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that such a report must be provided to Covered Entity within five (5) business days from the date of the breach or the date the breach should have been known to have occurred.

- f. Ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate on behalf of, Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- g. Provide access, at the request of Covered Entity and during normal business hours, 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 CFR §164.524, provided that Covered Entity delivers to Business Associate a written notice at least five (5) business days in advance of requesting such access. This provision does not apply if Business Associate and its employees, subcontractors and agents have no PHI in a Designated Record Set of Covered Entity.
- h. Make any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to pursuant to 45 CFR §164.526, at the request of Covered Entity or an Individual. This provision does not apply if Business Associate and its employees, subcontractors and agents have no PHI from a Designated Record Set of Covered Entity.
- i. Unless otherwise protected or prohibited from discovery or disclosure by law, Business Associate agrees to make internal practices, books, and records, including policies and procedures, relating to the use or disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, available to the Covered Entity or to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule or Security Rule. Business Associate shall have a reasonable time within which to comply with requests for such access and in no case shall access be required in less than five (5) business days after Business Associate's receipt of such request, unless otherwise designated by the Secretary.
- j. Maintain necessary and sufficient documentation of disclosures of PHI as would be required for Covered Entity to respond to a request by an Individual for an accounting of such disclosures, in accordance with 45 CFR §164.528.
- k. On request of Covered Entity, Business Associate agrees to provide to Covered Entity documentation made in accordance with 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 a request from Covered Entity and in no case shall Business Associate be required to provide such documentation in less than five (5) business days after Business Associate's receipt of such request.
- l. Except as provided for in this Agreement, in the event Business Associate receives an access, amendment, accounting of disclosure, or other similar request directly from an Individual, Business Associate will redirect the Individual to the Covered Entity.



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

- a. Except as otherwise limited by this Agreement, Business Associate may make any uses and disclosures of PHI necessary to perform its services to Covered Entity and otherwise meet its obligations under this Agreement, if such use or disclosure would not violate the Privacy Rule if done by Covered Entity. All other uses or disclosures by Business Associate not authorized by this Agreement or by specific instruction of Covered Entity are prohibited.
- b. 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.
- c. 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 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.
- d. Except as otherwise limited in this Agreement, Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 45 CFR §164.504(e)(2)(i)(B).
- e. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with §164.502(j)(1).

#### 5. **Obligations of Covered Entity.**

Covered Entity agrees to:

- a. Notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 CFR §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI.
- b. Notify Business Associate 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.
- c. Notify Business Associate of any restriction to the use or disclosure of PHI that Covered Entity has agreed to in accordance with 45 CFR §164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

#### 6. **Permissible Requests by Covered Entity**

Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy and/or Security Rules if done by Covered Entity.

#### 7. **Term and Termination.**

- a. Term. The Term of this Agreement shall be effective as of Effective Date 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



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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 Agreement.

- b. Termination for Cause. Notwithstanding any provision of this Agreement or the Base Agreement to the contrary, upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall give Business Associate written notice of such breach and provide reasonable opportunity for Business Associate to cure the breach or end the violation. Covered Entity may terminate this Agreement, and Business Associate agrees to such termination, if Business Associate has breached a material term of this Agreement and does not cure the breach or cure is not possible. If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.
- c. Effect of Expiration or Termination.
  - 1. Except as provided in paragraph (2) of this section, upon expiration or termination of this Agreement for any reason (including but not limited to, termination for cause, pursuant to Section (b) herein), Business Associate shall return or destroy all PHI received from, 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.
  - 2. In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity, within ten (10) business days, notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction 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. The provisions of this Section 7 (c) shall survive the expiration or termination of the Base Agreement (s) or this Agreement for any reason.

## 8. Miscellaneous.

- a. Regulatory References. A reference in this Agreement to a section in the Privacy Rule or Security Rule means the section as in effect or as amended.
- b. Amendment/Waiver. Notwithstanding any provision of this Agreement or the Base Agreement (s), as applicable, the Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule or Security Rule and the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, as amended from time to time and any privacy, security or other administrative simplification regulations promulgated pursuant thereto. No amendment shall be effective unless in writing and signed by duly authorized representatives of both Parties. No waiver by either Party of any breach of this Agreement, no matter how long continuing nor how often repeated, shall be deemed a waiver of any subsequent breach thereof, nor is delay or omission on the part of either Party to



exercise or insist on any right, power or privilege hereunder a waiver of such right, power or privilege.

- c. Survival. The respective rights and obligations of Business Associate under Section 7 (c) of this Agreement shall survive the termination of this Agreement.
- d. Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule or the Security Rule.
- e. Severability. If a court of competent jurisdiction finds any term of this Agreement invalid, illegal or unenforceable, that terms shall be curtailed, limited or deleted, but only to the extent necessary to remove the invalidity, illegality or unenforceability, and without in any way affecting or impairing the remaining terms.

9. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one original Agreement. Facsimile signatures shall be accepted and enforceable in lieu of original signatures.

This Agreement becomes binding when signed by duly authorized representatives of both Parties.

**Covered Entity**

**Otto Bock HealthCare**

By: \_\_\_\_\_

By: \_\_\_\_\_

\_\_\_\_\_  
Signature

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Signature

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Title

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