

# Business Associate Agreement

*Not applicable for Government agencies*

This Business Associate Agreement (“Agreement”) is entered into as of this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_ (“Effective Date”) between Phonak, LLC (“Business Associate”) and \_\_\_\_\_ (“Covered Entity”).

WHEREAS, Business Associate provides hearing instruments and related services (“Services”) to or on behalf of Covered Entity;

WHEREAS, in the course of providing Services to or on behalf of Covered Entity, Business Associate will have access to Individually Identifiable Health Information, as hereinafter defined, maintained by Covered Entity that is protected as confidential under the standards for privacy and security of Individually Identifiable Health Information promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 as set forth at 45 CFR Part 160 and Part 164 Subparts A, C and E (the “Privacy Standards” and the “Security Standards”), both as amended from time to time, including by Title XII, subtitle D, of the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”) and the regulations promulgated thereunder; and

WHEREAS, Covered Entity is required by the Privacy Standards and the Security Standards to enter into this Agreement and keep this Agreement in full force and effect in order to disclose and/or grant access to Individually Identifiable Health Information maintained by Covered Entity in connection with the performance of the Services; and

WHEREAS, this Agreement is intended to comply with the provisions of 45 CFR § 164.504(e).

Now, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

## 1. Definitions

- 1.1 Authorization. A document that satisfies the requirements of 45 C.F.R. 50S(a)(3)(ii), (c)(1) and (c)(2)
- 1.2 Breach. The acquisition, use, or disclosure of protected health information, subject to such further definition and limitation as set forth in 45 C.F.R.164.402.
- 1.3 Individual. The person who is the subject of Protected Health Information, as defined herein, and will include a person who qualifies as a personal representative pursuant to 45 CFR § 164.502(g).
- 1.4 Individually Identifiable Health Information. Information, including demographic information collected from an Individual, whether oral or recorded in any form or medium, that is:
  - 1.4.1 created or received by health care provider, health plan, employer or health care clearinghouse; and
  - 1.4.2 relates to the past, present, or future health or condition, whether physical or mental, of an Individual; the provision of health care to an Individual; or the past, present or future payment for the provision of health care to an Individual; and
  - 1.4.3 identifies the Individual or with respect to which there is a reasonable basis to believe the information can be used to identify the Individual.
- 1.5 Marketing. Any communication about a product or service that encourages recipients of the communication to purchase or use the product or service, subject to such further definition and limitation as set forth in 45 C.F.R.164.501 and 164.50S.
- 1.6 Protected Health Information. Individually Identifiable Health Information that is maintained or transmitted in any form or medium.
- 1.7 Secretary. The Secretary of the U.S. Department of Health and Human Services or his/her designee.

## 2. Obligations and Activities of Business Associate

- 2.1 Limitation on Use. Business Associate will not use or further disclose Protected Health Information other than as permitted or required by this Agreement or as required by law or regulation. To the extent Business Associate is to carry out Covered Entity's obligations under the Privacy Standards, Business Associate will comply with the requirements of the Privacy Standards that apply to the Covered Entity in the performance of such obligations.
- 2.2 Appropriate Safeguards. Business Associate will use appropriate safeguards to prevent use or disclosure of Protected Health Information other than as provided for by this Agreement.
- 2.3 Minimum Necessary. Business Associate represents and warrants that if it uses or discloses Protected Health Information, it will do so only in the minimum amount and to the minimum number of individuals necessary to perform its obligations to or on behalf of Covered Entity or as otherwise permitted or required by this Agreement or applicable law.
- 2.4 Mitigation of Harm. Business Associate will mitigate, to the extent practicable, any harmful effect that is known to Business Associate of use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- 2.5 Report of Breach. Business Associate will report to Covered Entity within fifteen (15) business days of discovery any use or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware. Business Associate will also report to Covered Entity within fifteen (15) business days of discovery any Breaches of unsecured Protected Health Information identified by Business Associate, including the names of the individuals whose Protected Health Information has been breached, as well as any other information about the nature and date of the Breach, the types of information involved, what individuals may do to protect themselves, and the steps the Business Associate is taking to mitigate the harm and protect against future Breaches, as provided by 42 U.S.C. 17932(b) and 45 C.F.R. 164.410.
- 2.6 Agents/Subcontractors. Business Associate will require that any agent, including subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees in writing to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such Protected Health Information.
- 2.7 Access to Books and Records. Upon request from the Secretary, Business Associate will make its internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, available to the Secretary in timely manner for purposes of the Secretary determining Covered Entity's compliance with the Privacy Standards.
- 2.8 Documentation of Disclosures. Business Associate will document disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information to the extent required by 45 CFR § 164.528.
- 2.9 Access to Information. Business Associate will make Protected Health Information maintained in a Designated Record Set (as defined in the Privacy Standards) available to Covered Entity or, as directed by Covered Entity, to an Individual to enable Covered Entity to fulfill its obligations in accordance with 45 CFR § 164.528.
- 2.10 Amendments. Business Associate will incorporate any amendments to Protected Health Information maintained in a Designated Record Set that Covered Entity directs or to which it agrees to enable Covered Entity to fulfill its obligations in accordance with 45 CFR § 164.526. Any denial of an individual's request for an Amendment of Protected Health Information will be the responsibility of the Covered Entity, including, but not limited to, resolution and/or reporting of all appeals and/or complaints arising therefrom.
- 2.11 Access to Protected Health Information. Business Associate agrees to make Protected Health Information available to an Individual in accordance with 45 CFR § 164.528.
- 2.12 Security Standards. As of the Effective Date of this Agreement, Business Associate will:
- 2.12.1 Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity;
  - 2.12.2 Ensure that any agent, including a subcontractor, to whom it provides such information agrees in writing to implement reasonable and appropriate safeguards to protect that information; and

2.12.3 Report to Covered Entity within fifteen (15) business days any Security Incident of which it becomes aware. The term "Security Incident" as used in this Agreement and as construed with respect to the term as defined in the Security Standards is subject to guidance or clarification from the Centers for Medicare and Medicaid Services.

### 3. Permitted Uses and Disclosure by Business Associate

3.1 Performance of Services. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform Services for or on behalf of Covered Entity, provided that such use or disclosure would not violate the Privacy Standards if done by Covered Entity.

3.2 Management and Administration. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information in providing Services under this Agreement as necessary for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate.

3.3 Compliance with Laws. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to report violations of law to appropriate Federal and State authorities or for any other purpose required by law, provided that such use or disclosure would not violate the Privacy Standards if done by Covered Entity.

### 4. Obligations of Covered Entity

4.1 Disclosure. Covered Entity represents and warrants that it will only disclose Protected Health Information to Business Associate to the extent permissible by law, including the Privacy Standards. Covered Entity will disclose Protected Health Information upon Business Associate's request or upon the request of third party if such disclosure is permissible by law, so that Business Associate may provide Services to or on behalf of Covered Entity, unless Covered Entity otherwise objects to the disclosure, or Business Associate is no longer providing services to Covered Entity.

4.2 Notice of Privacy Practices. Covered Entity will 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 Protected Health Information. Covered Entity will notify Business Associate within fifteen (15) business days of any change to its privacy practices that in any manner could impact Business Associate.

4.3 Marketing Authorizations. Covered Entity represents and warrants that it will not use or disclose Protected Health Information for the purposes of Marketing Phonak products to any Individual who has not given an Authorization for such Marketing, except for face-to-face communications between the Covered Entity and the Individual, where Covered Entity is receiving financial remuneration from Phonak for such Marketing.

4.4 Notice of Individual Revocations. Covered Entity will notify Business Associate within fifteen (15) business days of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.

4.5 Notice of Restrictions to Use. Covered Entity will notify Business Associate of any restriction to the use or disclosure of Protected Health Information 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 Protected Health Information. Covered Entity will notify Business Associate within fifteen (15) business days of any changes to restrictions to the use or disclosure of Protected Health Information to which Covered Entity agrees that in any manner could impact Business Associate.

4.6 No Impermissible Use. Covered Entity will not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Standards if done by Covered Entity.

### 5. Term and Termination

5.1 Term. This Agreement will commence as of the "Effective Date".

5.2 Termination. This Agreement will terminate when all of the Protected Health Information 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. If it is infeasible to return or destroy Protected Health Information, Business Associate will continue to extend the protections of this Agreement to such information, in accordance with the termination provisions in Section 6.2.

- 5.3 Termination for Cause. Upon Covered Entity's knowledge of a material breach of Business Associate of this Agreement, Covered Entity will either:
- 5.3.1 provide a reasonable opportunity for Business Associate to cure the breach or end the violation and terminate this Agreement;
  - 5.3.2 immediately terminate this Agreement if Business Associate has breached material term of this Agreement and cure is not possible; or
  - 5.3.3 if neither termination nor cure are feasible, Covered Entity will report the violation to the Secretary.
- 5.4 Return/Destruction of Information. Except as provided in Section 5.5 of this Agreement, and by regulations promulgated by the Food and Drug Administration, upon termination of this Agreement, for any reason, Business Associate will return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision will apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate will retain no copies of the Protected Health Information.
- 5.5 Return/Destruction Infeasible. In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate will provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the parties that return or destruction of Protected Health Information is infeasible, Business Associate will extend the protections of this Agreement to such Protected Health Information and limited further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.
- 5.6 Survival. The respective rights and obligations of Business Associate under Sections 5.4 and 5.5 of this Agreement will survive termination of this Agreement.
6. **Miscellaneous**
- 6.1 Regulatory references. A reference in this Agreement to a section in the Privacy Standards or Security Standards means the section as in effect or as amended.
- 6.2 Amendment. This Agreement may be amended only upon written agreement signed by both Parties; provided that the Parties agree to take such reasonable action as is necessary to amend this Agreement from time to time to enable Covered Entity to comply with the requirements of the Privacy Standards, the Security Standards, or any other applicable provisions of any other federal or state law.
- 6.3 Interpretation. Any ambiguity in this Agreement will be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Standards.
- 6.4 Entire Agreement. This Agreement, as amended from time to time pursuant to Paragraph 6.2, constitutes the entire agreement and understanding between the parties with respect to the Services specified and agreed upon in this Agreement and supersedes all prior oral or written agreements and understandings between them with respect to such services.
- 6.5 Severability. The invalidity of any portion of this document will not invalidate the remainder, and the remainder will continue in full force and effect.
- 6.6 Assignment. No party may assign or transfer any or all of its rights or obligations under this Agreement or any part of it, nor any benefit or interest in or under it, to any third party without the prior written consent of the other party which will not be unreasonably withheld.
- 6.7 Notices. Any notice which may be or is required to be given under this Agreement will be written and will be sent by first class mail return receipt requested, or by overnight courier. All notices will be effective upon receipt at the addresses stated below which may be changed from time-to-time upon thirty (30) days notice.
- 6.8 Headings. Headings are for convenience only and form no part of this Agreement and will not affect its interpretation.
- 6.9 Governing Law. This Agreement will be governed in accordance with the terms of any underlying agreement made between the parties wherein choice of law has already been negotiated and to which this Business Associate Agreement pertains, or if no previous choice of law provision exists, then in accordance with the substantive laws of the State of Incorporation of the Business Associate without regard to the conflicts of law principles.

IN WITNESS WHEREOF, the undersigned have executed this Agreement on the date and year set forth below.

## Phonak, LLC

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

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

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

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Notice To:

Legal Department & Chief Privacy Officer

4520 Weaver Parkway

Warrenville, IL 60555

Email: [privacy@phonak.com](mailto:privacy@phonak.com)

Phone: 630-821-5000

## Covered Entity

\_\_\_\_\_  
[Name of Covered Entity]

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

Print Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Notice To:

\_\_\_\_\_  
Email:

\_\_\_\_\_  
Phone: