

## **BUSINESS ASSOCIATE ADDENDUM**

Customer is a “Covered Entity” or “Business Associate” under the Health Insurance Portability and Accountability Act of 1996 and associated agency regulations promulgated thereunder, as amended, and the Health Information Technology for Economic and Clinical Health Act of 2009, Pub. Law 111-5 (the “HITECH Act”) (collectively, “HIPAA”). Pursuant to an underlying agreement (the “Agreement”) between Customer (also referred to herein as “Covered Entity”) and A/S, 3Shape TRIOS A/S, and 3Shape Medical A/S (together referred to herein as “3Shape” or “Business Associate”), 3Shape provides certain services to Customer and in providing those services may use, disclose, receive, create, maintain or transmit Protected Health Information (“PHI”) for or on behalf of Customer. When providing services to Customer that involve the use, disclosure, receipt, creation, maintenance or transmission to PHI for or on behalf of Customer, 3Shape is Customer’s “Business Associate” under HIPAA. In accordance with HIPAA (or “Applicable Law”), the parties have agreed to this Business Associate Agreement to protect PHI which 3Shape may handle in the performance of its duties for Customer. In this BAA, Covered Entity and Business Associate are each a “Party” and, collectively, are the “Parties”.

### **AGREEMENT**

**NOW, THEREFORE**, in consideration of the mutual covenants and conditions contained herein and the continued provision of PHI by Covered Entity to Business Associate under the Agreement in reliance on this BAA, the Parties agree as follows:

1. **Definitions.** For purposes of this BAA, the Parties give the following meaning to each of the terms in this Section 1 below. Any capitalized term used in this BAA, but not otherwise defined, has the meaning given to that term in HIPAA.
  - A. “Affiliate” means a subsidiary or affiliate of Covered Entity that is, or has been, considered a covered entity, as defined by HIPAA.
  - B. “Breach” means the acquisition, access, use, or disclosure of PHI in a manner not permitted under the Privacy Rule which compromises the security or privacy of the PHI, as defined in 45 CFR §164.402.
  - C. “Breach Notification Rule” means the portion of HIPAA set forth in Subpart D of 45 CFR Part 164.
  - D. “Data Aggregation” means, with respect to PHI created or received by Business Associate in its capacity as the “business associate” under HIPAA of Covered Entity, the combining of such PHI by Business Associate with the PHI received by Business Associate in its capacity as a business associate of one or more other “covered entity” under HIPAA, to permit data analyses that relate to the Health Care Operations (defined below) of the respective covered entities. The meaning of “data aggregation” in this BAA shall be consistent with the meaning given to that term in the Privacy Rule.

- E. “Designated Record Set” has the meaning given to such term under the Privacy Rule, including 45 CFR §164.501.
  - F. “De-Identify” means to alter the PHI such that the resulting information meets the requirements described in 45 CFR §§164.514(a) and (b).
  - G. “Electronic PHI” means any PHI maintained in or transmitted by electronic media as defined in 45 CFR §160.103.
  - H. “Health Care Operations” has the meaning given to that term in 45 CFR §164.501.
  - I. “HHS” means the U.S. Department of Health and Human Services.
  - J. “Individual” has the same meaning given to that term in 45 CFR § 160.103 and includes a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
  - K. “Privacy Rule” means that portion of HIPAA set forth in 45 CFR Part 160 and Part 164, Subparts A and E.
  - L. “Protected Health Information” or “PHI” has the meaning given to 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.
  - M. “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.
  - N. “Security Rule” means the Security Standards for the Protection of Electronic Health Information provided in 45 CFR Part 160 & Part 164, Subparts A and C.
  - O. “Unsecured Protected Health Information” or “Unsecured PHI” has the meaning given to the term “unsecured protected health information” in 45 CFR §164.402.
2. **Applicability.** This BAA supersedes the standard Data Processing and Business Associate Agreement addendum included as Appendix 1 to Business Associate’s standard General License Terms and Conditions and all prior understandings and agreements, written or oral, between the Parties with respect to its subject matter. Notwithstanding the foregoing, if Covered Entity and Business Associate negotiated and modified Business Associate’s standard Data Processing and Business Associate Agreement addendum (the “Negotiated Addendum”), then such Negotiated Addendum shall remain in effect until the parties explicitly agree in writing that this Business Associate Addendum amends and restates such Negotiated Addendum.

**3. Use and Disclosure of PHI.**

- A.** Except as otherwise provided in this BAA, Business Associate may use or disclose PHI as reasonably necessary to provide the services described in the Agreement to Covered Entity, and to undertake other activities of Business Associate permitted or required of Business Associate by this BAA or as required by law.
- B.** Except as otherwise limited in this BAA, Business Associate may also use PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate under the laws of the United States; to De-Identify such information for Business Associate's own business purposes or in connection with the Services; or to provide Data Aggregation services to Covered Entity as permitted by 45 C.F.R. 164.504(e)(2)(i)(b). Once PHI is De-Identified, it is no longer considered PHI.
- C.** Business Associate may disclose PHI for its proper management and administration, provided that (i) the disclosures are required by law; or (ii) Business Associate obtains, in writing, prior to making any disclosure to a third party (a) reasonable assurances from this third party that the PHI will be held confidential as provided under this BAA and used or further disclosed only as required by law or for the purpose for which it was disclosed to this third party and (b) an agreement from this third party to notify Business Associate immediately of any breaches of the confidentiality of the PHI, to the extent it has knowledge of the breach.
- D.** Business Associate will not use or disclose PHI in a manner other than as provided in this BAA, as permitted under the Privacy Rule, or as required by law. Business Associate will use or disclose PHI, to the extent practicable, as a limited data set or limited to the minimum necessary amount of PHI to carry out the intended purpose of the use or disclosure, in accordance with 45 C.F.R. 164.502(b) and 164.514(d).
- E.** Upon request, Business Associate will make available to Covered Entity any of Covered Entity's PHI that Business Associate or any of its agents or subcontractors have in their possession.
- F.** Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR §164.502(j)(1).
- G.** To the extent Business Associate is to carry out one or more of Covered Entity's obligations under the Privacy Rule, at Subpart E of 45 C.F.R. Part 164, Business Associate will comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligations.
- H.** Business Associate will not directly or indirectly receive remuneration for any PHI without a valid authorization from the Individual except in compliance with 45 CFR § 164.502 (a)(5)(ii). Business Associate will not engage in any communication which might

be deemed to be “marketing” under the HIPAA Rules without approval of Covered Entity.

- I. In the event that, on or after June 25, 2024, Business Associate receives a request for disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or disclosures to coroners and medical examiners and such PHI is potentially related to reproductive health care, Business Associate shall obtain an attestation from the requestor that such request is not for a prohibited purpose under 45 CFR § 164.502(a)(5)(iii).
4. **Safeguards Against Misuse of PHI.** Business Associate will use appropriate and reasonable safeguards to prevent the use or disclosure of PHI other than as provided by the Agreement or this BAA and Business Associate agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Electronic PHI that it creates, receives, maintains or transmits on behalf of Covered Entity.
5. **Reporting Disclosures of PHI and Security Incidents.** Business Associate will report to Covered Entity in writing any use or disclosure of PHI not provided for by this BAA of which it becomes aware and Business Associate agrees to report to Covered Entity any Security Incident affecting Electronic PHI of Covered Entity of which it becomes aware. Business Associate agrees to report any such event within five (5) business days of becoming aware of the event. The Parties acknowledge and agree that this Section deems notice to have been provided for the ongoing existence or occurrence of attempted but unsuccessful Security Incidents such as unsuccessful network pings, attack on Business Associate’s firewall, port scans, log-on attempts, denials of service or any combination of the above, so long as no such attempt results in unauthorized use, disclosure or Breach of electronic PHI, for which no additional notice to Covered Entity shall be required.
6. **Reporting Breaches of Unsecured PHI.** Business Associate will notify Covered Entity in writing promptly upon the discovery of any Breach of Unsecured PHI in accordance with the requirements set forth in 45 CFR §164.410, but in no case later than thirty (30) calendar days after discovery of a Breach.
7. **Mitigation of Disclosures of PHI.** Business Associate will take reasonable measures to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of any use or disclosure of PHI by Business Associate or its agents or subcontractors in violation of the requirements of this BAA.
8. **Agreements with Agents or Subcontractors.** Business Associate will ensure that any of its agents or subcontractors that have access to, or to which Business Associate provides, PHI agree in writing to the restrictions and conditions concerning uses and disclosures of PHI as contained in this BAA and agree to implement reasonable and appropriate safeguards to protect any

Electronic PHI that it creates, receives, maintains or transmits on behalf of Business Associate or, through the Business Associate, Covered Entity.

9. **Audit Report.** Upon request and no more than annually, Business Associate will provide Covered Entity, or upstream Business Associate, with a copy of its most recent independent HIPAA compliance report (AT-C 315), HITRUST certification or other mutually agreed upon independent standards based third party audit report. Covered entity agrees not to re-disclose Business Associate's audit report.

10. **Access to PHI by Individuals.**

- A. Upon request, Business Associate agrees to furnish Covered Entity with copies of the PHI maintained by Business Associate in a Designated Record Set in the time and manner reasonably designated by Covered Entity to enable Covered Entity to respond to an Individual's request for access to PHI under 45 CFR §164.524.
- B. In the event any Individual or personal representative requests access to the Individual's PHI directly from Business Associate, Business Associate within ten (10) business days, will forward that request to Covered Entity. Any disclosure of, or decision not to disclose, the PHI requested by an Individual or a personal representative and compliance with the requirements applicable to an Individual's right to obtain access to PHI shall be the sole responsibility of Covered Entity.

11. **Amendment of PHI.**

- A. Upon request and instruction from Covered Entity, Business Associate will amend PHI or a record about an Individual in a Designated Record Set that is maintained by, or otherwise within the possession of, Business Associate as directed by Covered Entity in accordance with procedures established by 45 CFR §164.526. Any request by Covered Entity to amend such information will be completed by Business Associate within fifteen (15) business days of Covered Entity's request.
- B. In the event that any Individual requests that Business Associate amend such Individual's PHI or record in a Designated Record Set, Business Associate within ten (10) business days will forward this request to Covered Entity. Any amendment of, or decision not to amend, the PHI or record as requested by an Individual and compliance with the requirements applicable to an Individual's right to request an amendment of PHI will be the sole responsibility of Covered Entity.

12. **Accounting of Disclosures.**

- A. Business Associate will document any disclosures of PHI made by it to account for such disclosures as required by 45 CFR §164.528. Business Associate also will make available

information related to such disclosures as would be required for Covered Entity to respond to a request for an accounting of disclosures in accordance with 45 CFR §164.528. At a minimum, Business Associate will furnish Covered Entity the following with respect to any covered disclosures by Business Associate: (i) the date of disclosure of PHI; (ii) the name of the entity or person who received PHI, and, if known, the address of such entity or person; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of the disclosure which includes the basis for such disclosure.

- B. Business Associate will furnish to Covered Entity information collected in accordance with this Section 12, within ten (10) business days after written request by Covered Entity, to permit Covered Entity to make an accounting of disclosures as required by 45 CFR §164.528.
  - C. In the event an Individual delivers the initial request for an accounting directly to Business Associate, Business Associate will within ten (10) business days forward such request to Covered Entity.
13. **Availability of Books and Records.** Business Associate will make available its internal practices, books, agreements, records, and policies and procedures relating to the use and disclosure of PHI, upon request, to the Secretary of HHS for purposes of determining Covered Entity's and Business Associate's compliance with HIPAA, and this BAA.
14. **Responsibilities of Covered Entity.** With regard to the use and/or disclosure of Protected Health Information by Business Associate, Covered Entity agrees to:
- A. Notify Business Associate of any limitation(s) in its notice of privacy practices 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 an Individual to use or disclose Protected Health Information, 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.
  - D. Except for data aggregation or management and administrative activities of Business Associate, Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under HIPAA if done by Covered Entity.

**15. Term and Termination.**

- A.** This BAA will become effective when accepted by Covered Entity, and will continue in effect until all obligations of the Parties have been met under the Agreement and under this BAA.
- B.** Covered Entity may terminate immediately this BAA, the underlying Agreement, and any other related agreements that involve the use or disclosure of PHI if Covered Entity makes a determination that Business Associate has breached a material term of this BAA and Business Associate has failed to cure that material breach, to Covered Entity's reasonable satisfaction, within thirty (30) days after written notice from Covered Entity.
- C.** If Business Associate determines that Covered Entity has breached a material term of this BAA, then Business Associate will provide Covered Entity with written notice of the existence of the breach and shall provide Covered Entity with thirty (30) days to cure the breach. Covered Entity's failure to cure the breach within the thirty (30) day period will be grounds for immediate termination of the Agreement and this BAA by Business Associate.
- D.** Upon termination of the Agreement or this BAA for any reason, all PHI maintained by Business Associate will be returned to Covered Entity or destroyed by Business Associate. Business Associate will not retain any copies of such information. This provision will apply to PHI in the possession of Business Associate's agents and subcontractors. Notwithstanding the foregoing, if return or destruction of the PHI is not feasible, in Business Associate's reasonable judgment, Business Associate will furnish Covered Entity with notification, in writing, of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of the PHI is infeasible, Business Associate will extend the protections of this BAA to such information for as long as Business Associate retains such information and will limit further uses and disclosures to those purposes that make the return or destruction of the information not feasible. The Parties understand that this Section 15.D. will survive any termination of this BAA.

**Miscellaneous.** This BAA is incorporated into the Agreement. The section titles used in this BAA are provided for convenience only and are not intended to affect the interpretation of any provision. Any and all references in this BAA to a statute or regulation mean the section as in effect or as amended. Nothing in this BAA is to be construed as conferring any right, remedy or claim on any person or entity other than the Parties and their respective successors and assigns. This BAA may only be assigned by a Party in accordance with the assignment provision of the Agreement. This BAA will be governed by the governing law set forth in the Agreement and any action brought under this Addendum will be brought in accordance the Agreement. The unenforceability of any provision in this Addendum will not affect the enforceability of any other provision. The waiver of any right or obligation under this BAA will not be deemed to be a

continuing waiver or the waiver of another right or obligation. All waivers must be in writing signed by both Parties.

16. **Notices.** All notices, requests and demands or other communications to be given under this BAA to a Party will be made to the email you provide when accepting this BAA.

If to Business Associate, to: [DPO@3shape.com](mailto:DPO@3shape.com).

17. **Fees and Costs.** Except as otherwise specified in the Agreement or this BAA, if any legal action or other proceeding is brought for the enforcement of this BAA, or because of an alleged dispute, contract violation, event, Breach, default, misrepresentation, or injunctive action, in connection with any of the provisions of this BAA, each party will bear their own legal expenses and the other cost incurred in that action or proceeding.
18. **Ambiguity.** Any ambiguity in this BAA related to amended or additional regulations will be resolved in favor of a meaning that permits a Party or the Parties to comply with HIPAA or any other law applicable to this BAA. The parties further agree that the language of this BAA shall not be construed presumptively against the drafter or any of the Parties to this BAA.
19. IN NO EVENT SHALL BUSINESS ASSOCIATE BE LIABLE TO COVERED ENTITY OR ANY THIRD PARTY FOR ANY ACT OR OMISSION THAT DOES NOT RISE TO THE LEVEL OF WILFUL MISCONDUCT OR GROSS NEGLIGENCE, OR FOR ANY INCIDENTAL, CONSEQUENTIAL, PUNITIVE, SPECIAL, EXEMPLARY OR OTHER INDIRECT DAMAGES OF ANY KIND OR NATURE INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS, LOSS OF DATA, LOSS OF BUSINESS, WHETHER A CLAIM FOR ANY SUCH LIABILITY OR DAMAGES IS PREMISED UPON BREACH OF CONTRACT, INDEMNITY, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER THEORIES OF LIABILITY, EVEN IF BUSINESS ASSOCIATE HAS BEEN APPRISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OCCURRING. Notwithstanding anything in this BAA to the contrary, in no event shall Business Associate's total liability arising from or relating to this BAA exceed an amount equal to amounts paid by Covered Entity to Business Associate for the service giving rise to the claim in the three (3) months prior to the event giving rise to the claim, whether a claim for any such liability or damages is premised upon breach of contract, indemnity, breach of warranty, negligence, strict liability, or any other theories of liability, even if Business Associate has been apprised of the possibility or likelihood of such damages occurring.
20. **Amendments.** Upon the effective date of any amendment or issuance of additional regulations ("change") to HIPAA, or any other law applicable to this BAA, Business Associate may amend this BAA. If Business Associate amends this BAA as a result of a change, such amended BAA will be presented to the Covered Entity when the Covered Entity next uses Business Associate's software and services. Covered Entity must accept the amended BAA to continue using Business Associate's software and services. If Covered Entity does not accept the amendment, Covered Entity must cease use of Business Associate's software and services. Notwithstanding the foregoing, if the cost to Business Associate to comply with the change is unreasonable, the



Parties shall negotiate Business Associate's fees or charges which will permit Business Associate to comply with the change. If the Parties cannot agree to new fees or charges, Business Associate may terminate this BAA and any underlying agreement for which this BAA is made a part.