

# Business Associate Agreement

This Business Associate Agreement (“BAA”) is entered into by and between \_\_\_\_\_ (the “Covered Entity”) and Comprehend PT Inc. (the “Business Associate”), a Delaware Corporation as of \_\_\_\_\_, 202\_\_ (the “Effective Date”).

## 1. PREAMBLE AND DEFINITIONS.

1.1 Pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), this BAA addresses the HIPAA requirements with respect to “business associates,” as defined under the privacy, security, breach notification, and enforcement rules 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 effect or as amended.

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. The functions, activities, and services that Business Associate performs for Covered Entity shall be defined in a separate agreement or work orders between Covered Entity and Business Associate (“Underlying Agreement”).

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 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 thirty (30) calendar days of "discovery" within the meaning of the HITECH Act. Such notice may 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. In addition, Business Associate may 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 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).

2.7 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, or to an individual at Covered Entity's request, information collected in accordance with this Section 2.7, 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 Electronic Health Record (as defined in Section 4) ("EHR") 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 directly from the Business Associate.

(d) In the case of an EHR that the Business Associate acquired on behalf of the Covered Entity as of January 1, 2009, paragraph (c) above shall apply to disclosures with respect to PHI made by the Business Associate from such EHR on or after January 1, 2014. In the case of an EHR that the Business Associate acquires on behalf of the Covered Entity after January 1, 2009, paragraph (c) above shall apply to disclosures with respect to PHI made by the Business Associate from such EHR on or after the later of January 1, 2011, or the date that it acquires the EHR.

2.8 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.

### **3. PERMITTED USES AND DISCLOSURES BY BUSINESS ASSOCIATE.**

3.1 Business Associate agrees to receive, create, use, or disclose PHI in a manner that is consistent with this BAA, the Privacy Rule, or Security Rule (as defined in Section 4) and 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 use or disclose PHI as Required By Law.

3.3 Business Associate agrees to make uses and disclosures and requests for PHI: Consistent with the minimum necessary standard specified in 45 C.F.R. § 164.502.

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.

3.5 Specific Other Uses and Disclosures:

(a) Business Associate is permitted to receive, create, use, or disclose PHI for the purpose of providing the services provided in the Underlying Agreement.

(b) Except as otherwise provided in this BAA, Business Associate is permitted to receive, create, use, or disclose PHI only in the limited circumstances in which Covered Entity makes a specific request in writing for the Business Associate’s services that requires Business Associate’s receipt, analysis, and/or transmission of PHI.

(c) Except as otherwise provided in this BAA, Business Associate may use PHI for its proper management and administration or to carry out its legal responsibilities as permitted under applicable law.

(d) Business Associate may use PHI to report violations of law to appropriate federal and state authorities, consistent with 45 C.F.R. § 164.502(j)(1).

#### **4. OBLIGATIONS OF COVERED ENTITY.**

##### **4.1 Covered Entity shall:**

(a) Provide Business Associate with any and all necessary and accurate information regarding the permitted uses and disclosures of PHI, to the extent necessary for Business Associate to fulfill its obligations under this BAA.

(b) Represent and warrant that it has obtained all necessary authorizations, consents, and permissions required under applicable law for the use and disclosure of PHI by Covered Entity and/or Business Associate, as contemplated under an Underlying Agreement.

(c) Provide Business Associate with the Notice of Privacy Practices that Covered Entity produces in accordance with the Privacy Rule, and any changes or limitations to such notice under 45 C.F.R. § 164.520, to the extent that such changes or limitations may affect Business Associate's use or disclosure of PHI.

(d) Notify Business Associate of any restriction on the use or disclosure of PHI that Covered Entity has agreed to or is required to comply with under 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI under this BAA.

(e) Notify Business Associate of any changes in or revocation of permission by an individual to use or disclose PHI, if such change or revocation may affect Business Associate's permitted or required uses and disclosures of PHI under this BAA.

4.2 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 Effective April 20, 2005, 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, 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 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 shall be liable under the civil and criminal enforcement provisions set forth at 42 U.S.C. § 1320d-5 and 1320d-6, as amended from time to time, for failure to comply with the safeguards, policies, and procedures requirements and any guidance issued by the Secretary from time to time with respect to such requirements;

(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. VERIFICATION AND ACCURACY.**

6.1 Business Associate acknowledges that the output generated by the application it utilizes is intended to provide recommendations based on the recorded conversation between the physical therapist and the patient. However, Business Associate does not guarantee, and Covered Entity acknowledges that Business Associate does not guarantee, the accuracy, completeness, or appropriateness of the information generated.

6.2 Covered Entity agrees to review and verify the output of the application for accuracy and completeness. It is the sole responsibility of Covered Entity to ensure that the generated documentation aligns with the actual patient visit and complies with applicable laws, regulations, and professional standards.

6.3 Business Associate shall not be liable for any errors, omissions, or inaccuracies in the generated output. The recommendations provided by Business Associate should not be considered a substitute for professional judgment, clinical expertise, or the independent verification of the accuracy of the generated documentation by Covered Entity.

## **7. INDEMNIFICATION.**

7.1 Covered Entity shall indemnify, defend, and hold harmless the Business Associate, its affiliates, and their respective officers, directors, members, and shareholders, ("Indemnified Parties"), from and against any and all losses, expense, damage, or injury (including, without limitation, all costs and reasonable attorneys' fees) that the Indemnified Parties may sustain as a result of, or arising out of (a) a breach of this BAA by Covered Entity or its agents; (b) Covered Entity's failure to notify any and all parties required to receive notification of any Breach of Unsecured PHI; or (c) any negligence or wrongful acts or omissions by Covered Entity or its agents, including without limitations, failure to perform Covered Entity's obligations under this BAA, the Privacy Rule, or the Security Rule.

7.2 Notwithstanding the foregoing, nothing in this Section shall limit any rights any of the Indemnified Parties may have to additional remedies under any other agreements between

Covered Entity and Business Associate or under applicable law for any acts or omissions of Covered Entity.

## 8. TERM AND TERMINATION.

8.1 This BAA shall be in effect as of the Effective Date, and shall terminate on the earlier of the date that:

(a) Either party terminates as authorized under Section 8.2.

(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 8.3.

8.2 This BAA may be terminated:

(a) Either party may terminate this BAA for any reason upon thirty (30) days written notice to the other party.

(b) 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 fifteen (15) 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.

8.3 Upon termination of this BAA for any reason, Business Associate, with respect to PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

(a) Retain only that PHI that is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities.

(b) Return to Covered Entity or, if agreed to by Covered Entity, destroy the remaining PHI that the Business Associate still maintains in any form.

(c) Continue 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 the PHI, other than as provided for in this Section 6, for as long as Business Associate retains the PHI.

(d) Not use or disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out at Section 3.5 above under "Specific Other Uses and Disclosures" which applied prior to termination.

(e) Return to Covered Entity or, if agreed to by Covered Entity, destroy the PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities.

(f) Ensure that the Subcontractor returns to Business Associate or, if agreed to by Business Associate, destroy the remaining PHI that the Subcontractor created, received, or maintained in any form.

8.4 The obligations of Business Associate under this Section 6 shall survive the termination of this BAA.

## 9. MISCELLANEOUS.

9.1 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.

9.2 The respective rights and obligations of Business Associate under Sections 7 and Section 8 of this BAA shall survive the termination of this BAA.

9.3 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.

9.4 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.

9.5 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.

9.6 This BAA may be executed in one or more counterparts, including via facsimile, PDF, or other electronic signature, each of which shall constitute original and all of which together shall constitute a single agreement.

9.7 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 New York. Any dispute, action, or claim

arising out of this BAA shall be adjudicated in a court of competent jurisdiction located within Erie County, New York

[SIGNATURE PAGE FOLLOWS]



IN WITNESS WHEREOF, the parties hereto have executed this BAA as of the date first above written.

**COVERED ENTITY:**

By \_\_\_\_\_

Name:

Title:

**BUSINESS ASSOCIATE:**

Comprehend PT Inc.

By \_\_\_\_\_

Name:

Title: