



TOTAL ANCILLARY

Clinic Profile

Legal Practice Name	
Do you have a preferred Sales Rep?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If yes, Enter Full Name	

Practice Name	Practice NPI	Practice TAX ID	Practice PTAN

Address	Street	City	State	Zip

Office Contacts	Last Name	First Name	Phone	Fax	Email
Practice Owner					
Office Manager/Admin					
Billing Contact					
Product Shipping Contact 1					
Product Shipping Contact 2					
Product Shipping Contact 3					

Physician Information				
Last Name	First Name	DPM/MD/DO/NP/PA	Individual NPI	Medicare PTAN

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (this “BAA”) is made and entered into effective as of _____ (“Effective Date”) by and between Total Ancillary Management, LLC (“Business Associate”), and _____ (“Covered Entity”), for purposes of complying with the privacy and security regulations of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 (“HITECH Act”), and the regulations promulgated thereunder by the U.S. Department of Health and Human Services (“HHS”) and corresponding regulations and guidance, all as may be amended from time to time.¹

RECITALS

WHEREAS, Business Associate acknowledges that Covered Entity has in its possession data that contains Individually Identifiable Health Information as defined by HIPAA and regulations promulgated thereunder; and

WHEREAS, Covered Entity and Business Associate have entered into, are entering into, or may subsequently enter into, agreements or other documented arrangements (collectively, the “Business Arrangements”) pursuant to which Business Associate may provide services for Covered Entity that may require Business Associate to access, create and/or Use health information that is protected by state and/or federal law; and

WHEREAS, pursuant to the Administrative Simplification provisions of HIPAA, HHS promulgated the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rules”), at 45 C.F.R. Parts 160 and 164, requiring certain Individuals and entities subject to the Privacy Rules (“Covered Entity”) to protect the privacy of certain Individually identifiable health information (“PHI”); and

WHEREAS, pursuant to HIPAA, HHS has issued the Security Rules (the “Security Rules”), at 45 C.F.R. Parts 160, 162 and 164, for the protection of electronic protected health information (“EPHI”); and

WHEREAS, the HITECH Act provides additional requirements in order to provide for the security of PHI and EPHI; and

WHEREAS, in order to protect the privacy and security of PHI and EPHI (collectively, “PHI”), created or maintained by or on behalf of Covered Entity, the Privacy Rules and Security Rules require a Covered Entity to enter into a business associate agreement with certain Individuals and entities who provide services for or on behalf of the Covered Entity when those services require the Use, Disclosure, creation, maintenance, and/or transmission of PHI; and

¹ See, particularly, “Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules,” 78 Federal Register, No. 17 (January 25, 2013) Final Rule (the “HIPAA Omnibus Final Rule”).

WHEREAS, Business Associate and Covered Entity desire to enter into this BAA in order to comply with HIPAA and the HITECH Act Rules and regulations (collectively, the “Privacy and Security Rules”).

NOW THEREFORE, in consideration of the mutual promises set forth in this BAA, and other good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, and in furtherance of the mutual intent of the parties to comply with the Privacy and Security Rules, Covered Entity and Business Associate agree as follows:

- A. Definitions. Terms used herein, but not otherwise defined, shall have the meaning ascribed by the HIPAA Privacy and Security Rules.
1. Breach means an acquisition, access, Use, or Disclosure of PHI that is not provided by this BAA and/or not permitted by the Privacy and Security Rules, and which compromises the security or privacy of PHI, unless an exception applies. However, a Breach does not include:
 - (a) Unintentional acquisition, access, or Use of PHI by an employee, Workforce member, or other individual acting under the authority of Business Associate (collectively, “Workforce”) if such acquisition, access, or Use was made in good faith and within the course and scope of the employment or other professional relationship of such employee, workforce member, or other Individual with Business Associate, and that Individual does not further Use or Disclose the PHI in violation of the Privacy and Security Rules; or
 - (b) Inadvertent Disclosure of PHI between employees of Business Associate, if they are authorized to access PHI and do not further Use or Disclose the PHI in violation of the Privacy and Security Rules; or
 - (c) Unauthorized Disclosures in which an unauthorized person to whom Protected Health Information is Disclosed would not reasonably have been able to retain the information.

Except as provided in Paragraph (A)(1) above, any acquisition, access, use or disclosure of PHI or EPHI in a manner not permitted by the Privacy and Security Rules is presumed to be a Breach unless Covered Entity or Business Associate, as applicable, demonstrates that the protected health information has not been compromised.

The parties intend the foregoing definition of “Breach” to be consistent with the HIPAA Privacy Rules and Security Rules, the HITECH Act, and HHS’ interpretations of those rules. To the extent that any part of the above definition is inconsistent with any of those laws, the laws and HHS interpretations of same shall govern.

2. Business Associate. shall generally have the same meaning as that term is defined at 45 C.F.R. § 160.103, and in reference to this BAA, shall mean Total Ancillary Management. “Business Associate” also includes a Subcontractor of Business Associate that creates, receives, maintains or transmits PHI on behalf of Business Associate.
3. Covered Entity. shall generally have the same meaning as the term “covered entity” is defined at 45 C.F.R. 160.103, and in reference to this BAA, shall mean _____.
4. Designated Record Set. means a group of records maintained by or for a Covered Entity that is: (i) the medical records and billing records about Individuals maintained by or for a covered health care provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the Covered Entity to make decisions about Individuals. For purposes of this definition, the term “record” means any item, collection, or grouping of information that includes protected health information and is maintained, collected, Used, or disseminated by or for a Covered Entity.
5. Electronic PHI (“EPHI”). is a subset of information covered by the Privacy Rule, i.e., all Individually identifiable health information (PHI) that a Covered Entity creates, receives, maintains or transmits in electronic form. The Security Rule does not apply to PHI that is transmitted orally or in writing.
6. Individual. means the person who is the subject of the Protected Health Information.
7. Privacy and Security Rules. The Privacy Rule, Security Rule and the HITECH Act are referred to collectively herein as the “Privacy and Security Rules,” and this defined term is meant to include any subsequent amendments to said statutes and regulations, and interpretations of same issued by HHS.
8. Protected Health Information (“PHI”). means Individually Identifiable Health Information that is transmitted or maintained in any form or medium, including electronic protected health information (“EPHI”). For purposes of this BAA, PHI includes only Individually Identifiable Health Information created and/or maintained by Covered Entity, that is provided to Business Associate by Covered Entity.
9. Required by Law. means a mandate contained in law that compels a Use or Disclosure of PHI.
10. Secretary. means the Secretary of HHS, or his or her Designee.
11. 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. It may or may not include a Breach of PHI or EPHI.

12. Unsecured PHI and EPHI. means PHI or EPHI that is not secured through the use of technologies or methodologies that render PHI unusable, unreadable, or indecipherable to unauthorized Individuals, which technologies or methodologies are specified in guidance issued by the Secretary of HHS at 74 Fed. Reg. 42741-43 (August 24, 2009), and as such may be updated or amended from time to time.
 13. Use. means, with respect to Individually Identifiable Health Information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.
- B. Purposes for which PHI May Be Disclosed to Business Associate. In connection with the services provided by Business Associate to or on behalf of Covered Entity as described in this BAA, Covered Entity may Disclose PHI to Business Associate.
- C. Obligations of Business Associate. Business Associate agrees to comply with applicable federal and state confidentiality and security laws, specifically including without limitation, the Privacy and Security Rules applicable to Business Associates, as delineated in said Rules, including, but not limited to:
1. Knowledge of the Privacy and Security Rules. Business Associate agrees to review and understand the Privacy and Security Rules as they apply to Business Associate, and to comply with applicable requirements of the Privacy and Security Rules, as well as any applicable amendments.
 2. Use and Disclosure of PHI. Business Associate agrees not to Use or Disclose PHI except as necessary to provide services to or on behalf of Covered Entity pursuant to this BAA or as Required by Law, and further agrees to make Uses, Disclosures and requests for PHI consistent with Covered Entity's minimum necessary policies and procedures.
- Furthermore, Business Associate agrees not to Use or Disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164, if done by Covered Entity, nor shall Covered Entity request Business Associate to make such Uses or Disclosures; provided, however, that Business Associate may Use and Disclose PHI (a) in providing data aggregation services relating to the health care operations of the Covered Entity; or (b) as necessary for the proper management and administration of Business Associate, or (c) to carry out its legal responsibilities, provided that:
- (a) the Use or Disclosure is Required by Law; or
 - (b) Business Associate obtains reasonable assurances from the person or entity to whom the PHI is Disclosed that: (i) the PHI will be held confidential and further Used and Disclosed only as Required by Law or for the purpose for which it was Disclosed to that person or entity; and (ii) the person or entity

will notify Business Associate of any instances, of which it is aware, as a result of which the confidentiality of the PHI has been breached.

Business Associate agrees to provide information to members of its workforce using or Disclosing PHI regarding the confidentiality requirements of the Privacy and Security Rules and this BAA and to notify the designated Privacy Officer of Covered Entity of any instances, of which it is aware, in which the PHI is Used or Disclosed for a purpose that is not otherwise provided for in this BAA or for a purpose not expressly permitted by the Privacy and Security Rules.

3. Minimum Necessary. Business Associate shall ensure that all Uses and Disclosures of PHI are subject to the principle of “minimum necessary Use and Disclosure,” i.e., only PHI that is the minimum necessary to accomplish the intended purpose of the Use, Disclosure, or request is Used or Disclosed.
4. De-identified Information. Business Associate may Use and Disclose De-identified Health Information if (a) the Use is disclosed to Covered Entity and permitted by Covered Entity in its sole discretion; and (b) the de-identification is in compliance with 45 C.F.R. §164.502(d), and the De-identified Health Information meets the standards and implementation specifications for de-identification under 45 C.F.R. §164.514(a) and (b), as amended from time to time.
5. Policies and Safeguards to Protect PHI. Business Associate shall maintain reasonable and appropriate safeguards to ensure that PHI is not Used or Disclosed other than as provided by this BAA or as Required by Law, including, specifically Subpart C of 45 C.F.R. Part 164. Specifically, Business Associate shall implement administrative, physical and technical safeguards that reasonably and appropriately:
 - (a) Ensure the confidentiality, integrity, and availability of all PHI that Business Associate creates, receives, maintains or transmits electronically, or in any other form, on behalf of Covered Entity;
 - (b) Identify and protect against reasonably anticipated threats to the security or integrity of the information;
 - (c) Protect against reasonably anticipated, impermissible Uses or Disclosures; and
 - (d) Ensure compliance by Business Associate’s work force by implementing certain “required” and “addressable” implementation specifications designed to protect the confidentiality, integrity and availability of EPHI within Business Associate’s organization.
6. Internal Practices, Policies and Procedures. Except as otherwise specified herein, Business Associate shall make available its internal practices, policies and procedures relating to the Use and Disclosure of PHI, received from or on behalf of Covered Entity to the Secretary or his or her agents for the purpose of

determining Covered Entity's compliance with the Privacy and Security Rules, or any other health oversight agency, or to Covered Entity. Records requested that are not protected by an applicable legal privilege will be made available in the time and manner specified by Covered Entity or the Secretary.

7. Agents and Subcontractors of Business Associate. If Business Associate Discloses PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity to agents, including Subcontractors, Business Associate shall require the agent or Subcontractor to agree in writing to the same restrictions, conditions, and requirements as apply to Business Associate under this BAA and the Privacy and Security Rules. Business Associate shall ensure that any agent, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity. Business Associate shall be liable to Covered Entity for any acts, failures or omissions of the agent or subcontractor in providing the services as if they were Business Associate's own acts, failures or omissions, to the extent permitted by law. Business Associate further expressly warrants that its agents or subcontractors will be specifically advised of, and will comply in all respects with, the terms of this BAA. At no time will Business Associate subcontract or otherwise assign work related to Covered Entity's PHI to any company providing that service outside the jurisdiction of United States law.
8. Individual Rights Regarding Designated Record Sets. If Business Associate maintains a Designated Record Set on behalf of Covered Entity, Business Associate agrees as follows:
 - (a) *Individual's Right to Copy or Inspect PHI.* Business Associate agrees that if it maintains a Designated Record Set for Covered Entity that is not maintained by Covered Entity, it will permit an Individual to inspect or copy PHI about said Individual in that Designated Record Set as directed by Covered Entity to meet the requirements of 45 C.F.R. § 164.524. Under the Privacy Rule, Covered Entity is required to take action on such requests as soon as possible, but not later than thirty (30) days following receipt of the request. Business Associate agrees to make reasonable efforts to assist Covered Entity in meeting this deadline. The information shall be provided in the form or format requested if it is readily producible in such form or format, or in summary form, if the Individual has agreed in advance to accept the information in summary form. A reasonable, cost-based fee for copying health information may be charged. If Covered Entity maintains the requested records, Covered Entity, rather than Business Associate, shall permit access according to its policies and procedures implementing the Privacy and Security Rules.
 - (b) *Individual Right to Amendment.* Business Associate agrees that, if it maintains PHI in a Designated Record Set, it will make such amendments to that PHI as may be requested and directed by Covered Entity pursuant to

45 C.F.R. §164.526, or take other measures as necessary to satisfy the Covered Entity's obligations under 45 C.F.R. §164.526. If Business Associate maintains a record in a Designated Record Set that is not also maintained by Covered Entity, Business Associate agrees that it will accommodate an Individual's request to amend PHI only in conjunction with a determination by Covered Entity that the amendment is appropriate according to 45 C.F.R. §164.526.

- (c) *Accounting of Disclosures.* Business Associate agrees to maintain documentation of the information required to provide an accounting of Disclosures of PHI in accordance with 45 C.F.R. §164.528, and to make this information available to Covered Entity upon Covered Entity's request, in order to allow Covered Entity to respond to an Individual's request for accounting of Disclosures. Under the Privacy Rule, Covered Entity is required to take action on such requests as soon as possible but not later than sixty (60) days following receipt of the request. Business Associate agrees to Use its best efforts to assist Covered Entity in meeting this deadline. Such accounting must be provided without cost to the Individual or Covered Entity if it is the first accounting requested by an Individual within any twelve (12) month period; however, a reasonable, cost-based fee may be charged for subsequent accountings if Business Associate informs the Individual in advance of the fee and is afforded an opportunity to withdraw or modify the request. Such accounting is limited to Disclosures that were made in the six (6) years prior to the request (not including Disclosures prior to the compliance date of the Privacy Rule) and shall be provided for as long as Business Associate maintains the PHI.

9. Business Associates' Performance of Covered Entity's Obligations under Subpart E of 45 C.F.R. §164. To the extent Business Associate is to carry out one or more of the Covered Entity's obligations 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 obligations.
10. Notice of Privacy Practices. Business Associate shall abide by the limitations of Covered Entity's Notice of Privacy Practices ("Notice"), of which it has knowledge. Any Use or Disclosure permitted by this BAA may be amended by changes to Covered Entity's Notice; provided, however, that the amended Notice shall not affect permitted Uses and Disclosures on which Business Associate relied prior to receiving notice of such amended Notice.
11. Data Aggregation. In the event Business Associate provides services for more than one Covered Entity, Business Associate is permitted to Use and Disclose PHI for data aggregation purposes after receiving written approval from Covered Entity and subject to the further limitation that the aggregated information does not extend to patient specific level of detail.

12. Withdrawal of Authorization. If the Use or Disclosure of PHI in this BAA is based upon an Individual's specific authorization for the Use or Disclosure of his or her PHI, and the Individual revokes such authorization, the effective date of such authorization has expired, or such authorization is found to be defective in any manner that renders it invalid, Business Associate shall, if it has notice of such revocation, expiration, or invalidity, cease the Use and Disclosure of the Individual's PHI except to the extent it has relied on such Use or Disclosure, or if an exception under the Privacy Rule expressly applies.
13. Security Incident. Business Associate agrees to immediately report to Covered Entity any successful "Security Incident," as defined by the HIPAA Security Rule, and to provide information to Covered Entity regarding unsuccessful Security Incidents, within thirty (30) days of a request for such report from Covered Entity.
14. Reporting Breaches of Unsecured PHI. If Business Associate has a Breach of Unsecured PHI, both as defined in Section A, Business Associate will report such Breach as provided in this Subsection. For purposes of this Subsection, a Breach shall be treated as discovered by the Business Associate as of the first day on which such Breach is known to Business Associate, or by exercising reasonable diligence, would have been known to Business Associate. Business Associate shall be deemed to have knowledge of a Breach if the Breach is known or by exercising reasonable diligence would have been known to any person, other than the person committing the Breach, who is an employee, officer, or other agent of Business Associate (determined in accordance with Federal common law of agency).
 - (a) *Reporting to Covered Entity.* Business Associate will report the Breach of Unsecured PHI to Covered Entity within five (5) days of Business Associate's discovering the Breach. Such report will include the following information:
 - (i) The identification of each Individual whose Unsecured PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired, Used, or Disclosed during the Breach, including the Individuals' contact information if available to the Business Associate;
 - (ii) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - (iii) A description of the types of Unsecured PHI involved in the Breach (such as name, Social Security number, date of birth, home address, or account number);
 - (iv) A brief description of what Business Associate is doing or has done to investigate the Breach, mitigate losses to Individuals and Covered Entity, and protect against any further breaches; and

- (v) Contact procedures for Individuals to ask questions or learn additional information about the Breach, which shall include a toll-free telephone number and an e-mail, website, or postal address at Business Associate. If Business Associate will report to Individuals directly under Subsection (b), Business Associate will include its notice in draft form.

(b) Reporting to Individuals.

- (i) Reporting by Business Associate. If PHI originating from more than one Covered Entity is involved in a Breach, the Business Associate will conduct the reporting on behalf of such Covered Entities, consistent with this subsection (b), so as to avoid duplicative reporting to Individuals by Covered Entities.
- (ii) Timing of Report. Business Associate will make such report without unreasonable delay after approval of the content under Subsection (C)(14)(b)(iii) by Covered Entity, if required, so that the parties can meet the requirement to report a breach no later than sixty (60) days after Business Associate discovers the breach. However, Business Associate may delay reporting to Individuals if a law enforcement official determines that reporting will impede a criminal investigation or cause damage to national security, in which case reporting may be delayed in the same manner as provided under 45 C.F.R. § 164.528(a)(2).
- (iii) Content of Report. Business Associate will include the following information in the report to Individuals:
 - a. A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - b. A description of the types of Unsecured PHI involved in the Breach (such as name, Social Security number, date of birth, home address, or account number, etc.);
 - c. A brief description of what Business Associate is doing or has done to investigate the Breach, mitigate losses to Individuals, and protect against any further breaches;
 - d. Steps Individuals should take to protect themselves from potential harm resulting from the Breach; and
 - e. Contact procedures for Individuals to ask questions or learn additional information about the Breach, which shall include

a toll-free telephone number and an e-mail, website, or postal address of Business Associate.

If the Report mentions the Covered Entity, Covered Entity will have the right to approve the Report in advance, which approval Covered Entity will not unreasonably withhold, condition or delay.

(iv) Method of Reporting to Individuals. Business Associate will provide the report to Individuals in writing, by first class mail, sent to the last known address of the Individual (or to the next of kin or personal representative, to the extent known, if the Individual is deceased). If an Individual has specified a preference for electronic mail in communications with the Business Associate and Business Associate has been informed of this preference, then Business Associate will use electronic mail. In cases where there is insufficient or out-of-date information to provide the written notice required, Business Associate will include a conspicuous posting on its website; or if it does not have a website, provide the required information to major print or broadcast media in geographic areas where the Individuals affected by the Breach likely reside. The website posting or media announcement will include a toll-free phone number so that affected Individuals may learn whether or not their unsecured PHI may have been included in the Breach.

(c) *Reporting to the Media.* If Business Associate believes that the Unsecured PHI of more than five hundred (500) Individuals residing within a state or jurisdiction of operation has been accessed, acquired, or Disclosed in the Breach, Business Associate will, within sixty (60) days of discovering the breach, provide notice to major print or broadcast media in geographic areas where the Individuals affected by the Breach likely reside. The media announcement will include a toll-free phone number so that affected Individuals may learn whether or not their Unsecured PHI may have been included in the Breach. If the Report mentions the Covered Entity, Covered Entity will have the right to approve the Report in advance, which approval Covered Entity will not unreasonably withhold, condition or delay.

(d) *Reporting to HHS.* If Business Associate believes that the Unsecured PHI of more than five hundred (500) Individuals residing within its jurisdiction of operation has been acquired or Disclosed in the Breach, Business Associate will notify the Secretary of HHS at the same time it makes its report to the Individuals. If the Report mentions the Covered Entity, Covered Entity will have the right to approve the Report in advance, which approval Covered Entity will not unreasonably withhold, condition or delay.

- (e) *Reimbursement to Covered Entity for Reporting Costs.* Business Associate will reimburse Covered Entity for any reasonable expenses Covered Entity incurs in notifying Individuals of a Breach caused by Business Associate or its Subcontractors or agents, and for any reasonable expenses required to mitigate harm to Individuals.
15. Covered Entity's Obligation to Keep Business Associate Informed. Covered Entity shall notify Business Associate of:
- (a) Any limitation(s) in the Notice of Privacy Practices of Covered Entity under 45 C.F.R. §164.520, to the extent that such limitation may affect Business Associate's Use or Disclosure of PHI.
 - (b) Any changes in, or revocation of, the permission by an Individual to Use or Disclose his or her PHI, to the extent that such changes may affect Business Associate's Use or Disclosure of PHI.
 - (c) Covered Entity shall notify Business Associate of any restriction on the Use or Disclosure of PHI that Covered Entity has agreed to or is required to abide under 45 C.F.R. §164.522, to the extent that such restriction may affect Business Associate's Use or Disclosure of PHI.

D. Term and Termination.

1. Term. This BAA shall be effective as of the Effective Date stated above and shall end when terminated pursuant to this Section.
2. Termination for Breach. If Business Associate breaches any material provision in this BAA, Covered Entity may, at its option, access and audit the records of Business Associate related to its Use and Disclosure of PHI, require Business Associate to submit to monitoring and reporting, and such other corrective actions as Covered Entity may determine are necessary to ensure compliance with this BAA, or Covered Entity may terminate this BAA on a date specified by Covered Entity.
3. Termination for Reasons Other Than Breach. Covered Entity and Business Associate agree that this BAA may be terminated by either party upon giving ninety (90) days written notice prior to the proposed termination date.
4. Effect of Termination. Upon termination of this BAA for any reason, Business Associate agrees to return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, or maintained by Business Associate in any form. This provision shall also apply to PHI/EPHI in the possession of Business Associate's Subcontractors or agents.
5. If Business Associate determines that it must Use or Disclose PHI for its own management and administration, or to carry out its legal responsibilities, Business Associate shall:

- a. Retain only that PHI which 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 PHI to prevent Use or Disclosure of the PHI, other than as provided for in this Section, for as long as Business Associate retains the PHI;
 - d. Not Use or Disclose any PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out in the sections discussing Business Associate's permitted Uses and Disclosures; and
 - 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.
6. Survival. The obligations of Business Associate under this Section shall survive the termination of this BAA.

E. Miscellaneous.

- 1. Indemnification. To the extent permitted by law, Business Associate agrees to indemnify and hold harmless Covered Entity from and against all claims, demands, liabilities, judgments or causes of action of any nature for any relief, elements of recovery or damages recognized by law (including, without limitation, attorney's fees, defense costs, and equitable relief), for any damage or loss incurred by Covered Entity arising out of, resulting from, or attributable to any acts or omissions or other conduct of Business Associate or its agents, including Subcontractors, in connection with the performance of Business Associate's or its agents', including Subcontractors', duties under this BAA. This indemnity provision shall survive termination of this BAA, and Covered Entity reserves the right, at its option and expense, to participate in the defense of any suit or proceeding through counsel of its own choosing.
- 2. Mitigation. If either party violates this BAA or the Privacy and Security Rules, each party agrees to mitigate any damage caused by such breach.
- 3. Rights of Proprietary Information. Covered Entity retains any and all rights to the proprietary information, confidential information, and PHI it releases to Business Associate.

5. Amendments. This BAA may not be changed or modified in any manner except by an instrument in writing signed by a duly authorized officer of each of the parties hereto. The parties, however, agree to amend this BAA from time to time as necessary, in order to allow Covered Entity to comply with the requirements of the Privacy and Security Rules. The parties recognize that the HITECH Act requires the Secretary of HHS to promulgate regulations that may expand the requirements of the Privacy and Security Rules. At such time during the term of this BAA that regulations take effect which are interpreted by any party, based on an opinion from legal counsel, as changing or expanding the Privacy and Security Rules requirements under this BAA, then the parties will, within ten (10) days following notice to the other, in good faith, attempt to amend the BAA to provide for compliance with such expanded requirements.
6. Choice of Law. This BAA AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES, SHALL BE GOVERNED BY AND INTREPRETED UNDER THE LAWS OF THE STATE OF TEXAS. ANY SUIT OR LITIGATION RELATED TO OR ARISING OUT OF THIS AGREEMENT MUST BE FILED IN A COURT IN DALLAS COUNTY, TEXAS, AND THE PARTIES AGREE THAT THIS MANDATORY VENUE PROVISION IS ENFORCEABLE.
7. Notices. All notices provided for hereunder shall be made in writing, and shall be deemed to have been duly given and received (a) on the date of service if served personally on the party to whom notice is to be given, (b) on the date of service if delivery is made by overnight courier to the party to whom notice is to be given at the address set forth below, or (c) five (5) days after the date of depositing the same in the U.S. Mail and mailing to the party to whom notice is to be given, by First Class Mail, registered or certified, postage prepaid, and properly addressed to the address set forth below.

If to Covered Entity: Attn: _____

If to Business Associate:
Attn: Chad Herron
Total Ancillary Management, LLC
3151 Halifax Street, Suite 140
Dallas, Texas 75247

Either party may change its address from that stated above by giving written notice of the change to the other in the manner provided in this section.

8. Nature of BAA. Nothing in this BAA shall be construed to create (a) a partnership, joint venture or other joint business relationship between the parties or any of their affiliates, (b) any fiduciary duty owed by one party to another party or any of its affiliates, or (c) a relationship of employer and employee between the parties.
9. No Waiver. Failure or delay on the part of either party to exercise any right, power, privilege or remedy hereunder shall not constitute a waiver thereof. No provision

of this BAA may be waived by either party except by a writing signed by an authorized representative of the party making the waiver.

10. Severability. The provisions of this BAA shall be severable, and if any provision of this BAA is held or declared to be illegal, invalid or unenforceable, the remainder of this BAA shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.
11. No Third Party Beneficiaries. Nothing in this BAA shall be considered or construed as conferring any right or benefit on a person not party to this BAA nor imposing any obligations on either Party hereto to persons not a party to this BAA.
12. Headings. The descriptive headings of this BAA are for convenience only, do not constitute a part of this BAA, and shall not affect in any way the meaning or interpretation of this BAA.
13. Interpretation. Any ambiguity in this BAA shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy and Security Rules and any applicable state confidentiality laws. The provisions of this BAA shall prevail over the provisions of any other BAA that exists between the Parties that may conflict with, or appear inconsistent with, any provision of this BAA or the Privacy and Security Rules as they pertain to PHI.
14. Regulatory References. A citation in this BAA to the Code of Federal Regulations and/or other laws shall mean the cited section as that section may be amended from time to time.
15. Entire Agreement. This BAA constitutes and expresses the entire agreement of the parties hereto with respect to the subject matter hereof, and there are no representations, inducements, promises, agreements, arrangement, undertakings, covenants or conditions concerning the subject matter hereof, whether oral or written, express or implied, that are not incorporated herein or superseded hereby. Any and all prior agreements are hereby terminated unless attached hereto and incorporated by amendment. This BAA may only be amended by written consent of all parties hereto.
16. Counterparts. This BAA may be executed in any number of counterparts, each of which may be executed by less than all of the parties, all of which together will constitute one instrument. This BAA may be executed by facsimile signature or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., www.docusign.com), such signature is deemed an original signature. Copies of the execution copy of this BAA with one or more signatures sent by facsimile transmission or as a "PDF" (portable document file) attached to an electronic mail message or other transmission method and any counterpart so delivered is deemed to have been duly and validly delivered and is valid, fully enforceable, and effective for all purposes without a manually executed original.

Standing Orders



1. Purpose:

- To order and Process products from vendors/manufacturers using a centralized ordering system as opposed to individual clinics ordering products directly.

2. Policy:

- _____ allows Total Ancillary Management LLC to manage administrative functions that allow the locations to purchase products and supplies in order to treat patients.

3. Procedure:

- Total Ancillary shall process Benefits Verification Forms in order to determine insurance eligibility and coverage for patients that require certain products for treatment as ordered by a qualified health care provider.
- Total Ancillary shall submit Purchase Orders for product ordering.
- Total Ancillary shall receive invoices for all products ordered.
- Total Ancillary shall reconcile all invoice statuses with manufacturers.
- Total Ancillary is protected under BAA with clinic and can discuss PHI on behalf of clinic.

Standing Order Authorization

This policy and procedure shall remain in effect for all patients of _____

Effective Start Date _____ Until rescinded or until _____

Physician Name _____

Signature _____

Date _____

IN WITNESS WHEREOF, the parties have executed this BAA on the dates set forth below, effective on the Effective Date first stated above.

Business Associate: Total Ancillary Management LLC

Covered Entity:

Signature:

Signature:

Printed Name:

Printed Name:

Title:

Title:

Date:

Date:

CUSTOMER PRICING AGREEMENT

Product ID	ProductName	Product Description	Product Size	Unit	Price
74745-0051-01	Helicoll	Bovine Type I Colhgm	1.27sq cm disc	2	\$1,700
74745-0101-01	Helicoll	Bovine Type I Colhgm	2.54sq cm disc	5	\$4,250
HCO.2x1.6	Helicoll	Bovine Type I Colhgm	2x4	8	\$6,800
HC1.2x1.6	Helicoll	Bovine Type I Colhgm	3x4	12	\$10,200
HC1.6x1.6	Helicoll	Bovine Type I Colhgm	4x4	16	\$13,600
HC2x2	Helicoll	Bovine Type I Colhgm	5x5	25	\$21,250
HC2x4	Helicoll	Bovine Type I Colhgm	5x10	50	\$42,500



STANDARD TERMS AND CONDITIONS OF SALE

1. The Customer as the “Buyer” or “Customer” and Mindsight Medical, LLC as the “Seller”, whereby both are deemed a “Party” individually and collectively the “Parties”, agree to the following:

2. Acceptance.

SELLER’S ACCEPTANCE OF BUYER’S PURCHASE ORDER IS EXPRESSLY MADE CONDITIONAL ON BUYER’S ACCEPTANCE OF THE FOLLOWING TERMS AND CONDITIONS OF SALE, WHICH ARE IN LIEU OF ANY ADDITIONAL OR DIFFERENT TERMS CONTAINED IN BUYER’S PURCHASE ORDER OR OTHER DOCUMENT OR COMMUNICATION PERTAINING TO BUYER’S ORDER OR THE GOODS. BUYER’S ASSENT TO THE TERMS AND CONDITIONS CONTAINED IN THIS DOCUMENT SHALL BE CONCLUSIVELY PRESUMED FROM BUYER’S ACCEPTANCE OF ALL OR ANY PART OF THE GOODS OR FROM PAYMENT BY BUYER FOR ALL OR ANY PART OF THE GOODS. NONE OF THESE TERMS AND CONDITIONS MAY BE ADDED TO, MODIFIED, SUPERSEDED OR OTHERWISE ALTERED, EXCEPT BY A WRITTEN INSTRUMENT SIGNED BY AN AUTHORIZED EXECUTIVE OF SELLER. FAILURE OF SELLER TO OBJECT TO ANY TERMS OR CONDITIONS WHICH MAY BE CONTAINED IN ANY DOCUMENT OR FORM OF BUYER SHALL NOT BE CONSTRUED AS A WAIVER OF THESE CONDITIONS, NOR AS AN ACCEPTANCE OF ANY SUCH TERMS AND CONDITIONS.

3. Payment Terms.

Payment is due Net Forty Five(45) days from date of shipment.

All amounts due and owing are deemed late commencing on day Forty Six(46) days from the date of shipment (“Late Payment Date”). Seller shall accrue interest from such Late Payment Date at the rate of 1.5% per month multiplied by the amount due (which shall include principal and all prior interest accrued but unpaid) or the maximum amount allowed by applicable law, whichever is less, until paid.

4. Warranty.

Seller warrants that the goods supplied under this invoice (the “Goods”) are regulated under 21 C.F.R. Part 1271 as human cells, tissues, and cellular and tissue-based products (HCT/Ps) and shall conform to all applicable U.S. Food and Drug Administration requirements. THE FOREGOING WARRANTY IS SELLER’S SOLE WARRANTY WITH RESPECT TO THESE GOODS. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED. SELLER’S LIABILITY FOR BREACH OF WARRANTY HEREUNDER IS LIMITED SOLELY TO THE REPLACEMENT OF THE NON-CONFORMING GOODS, WHICH SHALL BE RETURNED TO SELLER’S FACILITY, TRANSPORTATION CHARGES PREPAID BY BUYER.

5. LIMITATION OF LIABILITY.

EXCEPT FOR LIABILITY ARISING OUT SELLER'S GROSS NEGLIGENCE OR WILFULL MISCONDUCT, SELLER'S LIABILITY TO BUYER, WHETHER IN CONTRACT, IN TORT, UNDER ANY WARRANTY, IN NEGLIGENCE OR OTHERWISE, SHALL NOT EXCEED IN ANY CASE THE RETURN OF THE AMOUNT OF THE PURCHASE PRICE PAID BY BUYER FOR ALL PRODUCTS PURCHASED FROM SELLER DURING THE PREVIOUS TWELVE (12) MONTHS AND UNDER NO CIRCUMSTANCES SHALL SELLER BE LIABLE FOR SPECIAL, IN DIRECT OR CONSEQUENTIAL DAMAGES. THE PRICE STATED FOR THE GOODS IS CONSIDERATION FOR LIMITING SELLER'S LIABILITY.

6. Claims.

Claims by Buyer for shortages or errors in delivery must be made to Seller via electronic mail within ten (10) days after the delivery of the Goods.

7. Consignments.

If the Buyer is granted the option of consigned inventory; this consigned inventory will be subject to a separate consignment agreement.

8. Returns.

Customer may return product to Mindsight within 30 days of the original invoice date. No Goods shall be returned for credit without first obtaining authorization from Seller's Customer Service department. In order for the product to qualify for a reimbursement or credit of the amount paid by customer, product must be in its original condition, unopened, have no markings, and have confirmation that it was properly stored. Frozen tissue products and expired products are not able to be accepted for return.

9. Shipment.

Delivery terms are F.O.B. Seller's point of shipment at Seller's distribution facility. Title and risk of loss shall pass to Buyer upon delivery of Goods to carrier. Buyer shall pay actual, invoiced, freight charges from the point of shipment to the point of delivery.

10. Security Interest.

Shipments by Seller shall at all times be subject to the approval of and requirements of the credit department of Seller, including the requirement that Buyer pay part or all of the purchase price in advance. Seller retains a purchase money security interest in all Goods not paid for in full, notwithstanding that the goods have been delivered to Buyer, and Buyer hereby authorized Seller to execute and file financing statements describing the Goods, and other document which may be requested by Seller to evidence its security interest.

11. Cancellation.

Orders accepted by Seller are subject to cancellation by Buyer only upon the express written consent of Seller. Upon such cancellation and consent, Seller shall cease work and hold for Buyer all completed and partially completed articles and work in progress and Buyer shall pay Seller: for all work and materials that have been committed to and/or identified to Buyer's order plus a cancellation charge as prescribed by Seller, in addition to a reasonable profit to Seller on the entire contract.

12. Indemnification.

Each Party (the “Indemnifying Party”) agrees to save and hold the other Party (the “Indemnified Party”) harmless from any claims, demands, liabilities, costs, expenses or judgments arising in whole or in part, directly or indirectly, out of the gross negligence or wilfull misconduct by Indemnifying Party or it’s customers, agents, employees or invitees. This indemnification shall include all costs, attorney’s fees and other expenses paid or incurred by or imposed upon Indemnified Party in connection with the defense of any such claim

13. Governing Law.

THIS AGREEMENT, AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES, SHALL BE GOVERNED BY AND INTREPRETED UNDER THE LAWS OF THE STATE OF TEXAS. ANY SUIT OR LITIGATION RELATED TO OR ARISING OUT OF THIS AGREEMENT MUST BE FILED IN A COURT IN DALLAS COUNTY, TEXAS, AND THE PARTIES AGREE THAT THIS MANDATORY VENUE PROVISION IS ENFORCEABLE.

14. Default.

In the case of default or breach by Buyer in the performance of any or all of the provisions of this agreement, including non-payment by the Late Payment Date of any outstanding invoice, Seller may cancel any outstanding order from Buyer and declare all obligations immediately due and payable. Buyer shall in addition, be liable for Seller’s expenses incurred in exercising any remedies available to it, including reasonable attorney’s fees and legal expenses. All unpaid obligations shall bear interest at the contract rate provided under terms of payment above.

15. Dispute Resolution.

If any controversy should arise between Buyer and Seller in the terms and conditions, obligations, performance, interpretation, or application of this Agreement, the Parties hereby agree to make a good faith effort to resolve any such controversy between the Parties with a maximum time span of 60 days past the Late Payment Date, the “Good Faith Window” If after the Good Faith Window, the Parties are still unable to resolve any such controversy, either Party may serve upon the other party a written notice stating that such party desires to submit the controversy to the dispute resolution process described herein. In that event, the parties hereby agree to submit any such dispute to mediation under the AHLA Alternative Dispute Resolution Service Rules of Procedure for Mediation (the “**Procedures**”). If any dispute is not resolved by mediation on or before (60) days after it is submitted to the AHLA for resolution, the dispute shall by submitted to arbitration in accordance with the AHLA Alternative Dispute Resolution Service Rules of Procedure for Arbitration. The same person may serve both as the mediator and the arbitrator. Each party will pay an equal share of any costs incurred as a result of mediation or arbitration under this Agreement. THIS CONTRACT CONTAINS A BINDING ARBITRATION PROVISION WHICH MAY BE ENFORCED BY THE PARTIES.

16. Product Assurance.

See SCHEDULE A

SCHEDULE A

Assurance on Benefit Verification and Prior Authorization Program

- In the event a third-party payor or Medicare denies coverage due solely to an error made by Mindsight Medical, LLC ("Mindsight") in researching and summarizing whether and under what circumstances and criteria (e.g. prior authorization, FDA-approved use) product is covered by the patient's insurance, Mindsight will credit the provider for its costs incurred specific to the products used to treat such patient.
- In order to be eligible for a credit, (i) the Provider must have provided Total Ancillary complete and accurate patient information on the Benefit Verification Request Form for each date of service, (ii) Total Ancillary must have verified the patient's benefits with his/her insurance and obtained prior authorization on behalf of the Provider for the use of Mindsight Products for the patient, if required by the patient's insurance, (iii) the Provider's use of Mindsight Products for the patient must have been fully compliant with all of the patient's insurance criteria, and (iv) the Provider must notify Total Ancillary of the third party payor's denial of coverage within three months from the corresponding patient's procedure date.
- Under the Assurance on Benefit Verification and Prior Authorization Program, Mindsight, and its affiliates do not guarantee reimbursement.
- Additional conditions and limitations apply:
 - Claim and EOB must be submitted to Total Ancillary for review at billing@totalancillary.com.
 - First level of appeal must be filed within insurance requirements.
 - Denial of appeal from payers needs to be sent to Total Ancillary.
 - Must agree to report the credit to the appropriate government payer or secondary insurer.
 - Must return any collected deductibles and co-payment to the patient and/or adjust the statement submitted to the government.
 - This program excludes all Medicaid cases (primary and secondary.)
 - Limited to cases that are on-label and in accordance with the conditions of coverage notes in the applicable local coverage determinations (LCD's) and medical policies for all products listed on the Product Pricing Agreement
 - Credits are limited to the purchase price for the product: do not cover any further patient care expenses or costs related to therapy. Provider must accept assignment/contracted rate.
 - Must be in accordance with the payer's documentation criteria.
- For more information about the Assurance on Benefit Verification and Prior Authorization Program, including how to apply for a credit under the Program, contact Total Ancillary at billing@totalancillary.com.

**TOTAL ANCILLARY**

BUSINESS CREDIT APPLICATION

_____ Company Name			_____ Address			_____ Phone Number											
_____ Billing Address						_____ Shipping Address											
_____ City			_____ State			_____ Zip			_____ City			_____ State			_____ Zip		
_____ Accounts Payable Contact									_____ Accounts Payable Phone Number & Fax Number								
Type of Ownership: ____ Corporation ____ Partnership ____ Sole Proprietor-Owner's Name: _____ ____ Government ____ Non-Profit Years in Business _____																	
In the previous 5 years, have you done business under another name? ____ Yes ____ No																	
If yes, please provide previous business name: _____																	

BANK REFERENCE

_____ Name			_____ Phone Number			_____ Fax Number		
Account Number: _____						Contact: _____		

OPEN ACCOUNT REFERENCES

1. _____	_____ Name			_____ Phone Number			_____ Fax Number		
	_____ Address			_____ City			_____ State _____ Zip		
2. _____	_____ Name			_____ Phone Number			_____ Fax Number		
	_____ Address			_____ City			_____ State _____ Zip		
3. _____	_____ Name			_____ Phone Number			_____ Fax Number		
	_____ Address			_____ City			_____ State _____ Zip		

Dun & Bradstreet Number: _____		Tax ID #: _____	
Authorized Signature: _____		Date: _____	
Print Name: _____		Title: _____	

INTER-OFFICE USE ONLY	Date: _____
Credit Limit: _____	Approved by: _____

SUBMIT TO SALES@TOTALANCILLARY.COM OR FAX TO 800.630.8490



TOTAL ANCILLARY

GRAFT APPLICATION LOG

CLINIC NAME: _____ **LOCATION:** _____

PATIENT NAME: _____ **PHYSICIAN:** _____

Date: _____ Product: _____ Date Billed: _____	APPLICATION 1	Date: _____ Product: _____ Date Billed: _____	APPLICATION 2
Date: _____ Product: _____ Date Billed: _____	APPLICATION 3	Date: _____ Product: _____ Date Billed: _____	APPLICATION 4
Date: _____ Product: _____ Date Billed: _____	APPLICATION 5	Date: _____ Product: _____ Date Billed: _____	APPLICATION 6
Date: _____ Product: _____ Date Billed: _____	APPLICATION 7	Date: _____ Product: _____ Date Billed: _____	APPLICATION 8

SUBMIT WEEKLY TO

Sales@TotalAncillary.com or Fax to 800.630.8490



CUSTOMER PRICING AGREEMENT

Signature Page

Customer Name: _____

This Agreement is for the purchase of the products listed on the Mindsight Medical product agreement, enforceable by its terms and conditions when signed on behalf of both the customer and MindSightMedical, LLC.

This Agreement is subject to the terms and conditions, see attachments.

Client

MindSight Medical, LLC

Signature: _____

Name: _____

Title: _____

Date: _____

Signature: _____

Name: _____

Title: _____

Date: _____