

## BUSINESS ASSOCIATE AGREEMENT

THIS AGREEMENT is entered into on this \_\_\_\_\_ day of \_\_\_\_\_, 2003, between \_\_\_\_\_ ("Facility") and **Orthotics & Prosthetics One, Inc.** ("Business Associate").

### WITNESSETH:

WHEREAS, Facility is a Corporation / Partnership / Sole Proprietorship organized/incorporated under the law of [STATE] \_\_\_\_\_ which is in the business of providing orthotic/prosthetic patient care services, Business Associate is incorporated under the law of Iowa which is in the business of custom fabricating, manufacturing, and selling orthotic and prosthetic devices; and

WHEREAS, Facility will make available and/or transfer to Business Associate certain information, in conjunction with manufactured goods or services that are being provided by Business Associate to Facility, that is confidential and must be afforded confidential treatment and protection in accordance with the Standards for Privacy of Individually Identifiable Health Information (the "Privacy Rule") under the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA").

WHEREAS, Business Associate will have access to and/or receive from Facility certain information that can be used or disclosed only in accordance with this Agreement and the Privacy Regulations.

**NOW, THEREFORE**, Facility and Business Associate for good and valuable consideration as set forth in this Agreement, and intending to be bound, agree as follows:

### 1. DEFINITIONS

(a) **Business Associate.** "Business Associate" shall mean **Orthotics & Prosthetics One, Inc.**

(b) **Facility.** "Facility" shall mean \_\_\_\_\_.

(c) **Individual.** "Individual" shall have the same meaning as the term "individual" in 45 CFR § 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

(d) **Privacy Rule.** "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E, as in effect from time to time.

(e) **Protected Health Information.** "Protected Health Information" or "PHI" shall have the same meaning as the term "protected health information" in 45 CFR § 164.501, limited to the information created/received by Business Associate from or on behalf of Facility.

(f) **Required By Law.** "Required By Law" shall have the same meaning as the term "required by law" in 45 CFR § 164.501.

(g) **Secretary.** "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.

### 2. GENERAL LIMIT ON USE AND DISCLOSURE ESTABLISHED BY TERMS OF AGREEMENT

Business Associate hereby agrees that it shall be prohibited from using or disclosing the PHI provided or made available by Facility for any purpose other than as expressly permitted or required by this Agreement.

### 3. GENERAL USE AND DISCLOSURE

#### (a) Permitted Uses and Disclosures of Business Associate

Except as otherwise limited in the Agreement, Business Associate shall be permitted to use and/or disclose PHI on behalf of, or to provide services to, Facility for the purposes of fulfilling its obligations to produce, repair, and service custom fitted and custom fabricated orthoses, prostheses, and components of orthoses, and prostheses, and related services to Facility, if such use or disclosure of PHI would not violate the Privacy Rule.

**(b) Uses for Proper Management and Administration**

Except as otherwise limited in the Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.

**(c) Disclosures of PHI for Management and Administration**

Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

**(d) Data Aggregation**

Except as otherwise limited in the Agreement, Business Associate may use PHI to provide Data Aggregation services to Facility as permitted by 42CFR 164.504(e)(2)(i)(B).

**4. OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE**

**(a) No further Use or Disclosure:**

Business Associate agrees to not use or further disclose PHI provided or made available by Facility other than as permitted or required by the Agreement or as required by Law.

**(b) Appropriate Safeguards:**

Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the PHI, other than as provided for by this Agreement.

**(c) Reports Of Improper Use Or Disclosure:**

Business Associate hereby agrees that it shall promptly report to Facility any use or disclosure of PHI not provided for or allowed by this Agreement of which the Business Associate becomes aware.

**(d) Subcontractors And Agents:**

Business Associate hereby agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created, or received by Business Associate on behalf of the Facility, agrees to the same terms, conditions and restrictions that apply through this Agreement to Business Associate with respect to such information.

**(e) Access To Books And Records:**

Business Associate hereby agrees to make its internal practices, books, and records relating to the use or disclosure of PHI received from, or created or received by Business Associate on behalf of the Facility, available to the Facility, or at the request of the Facility to the Secretary, in a time and manner negotiated by the Facility and Business Associate or designated by the Secretary, for purposes of the Secretary determining the Facility's compliance with the Privacy Rule.

**(f) Provide Accounting:**

(i) Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for Facility to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with the Privacy Rule.

(ii) Business Associate agrees to provide to Facility or an Individual, in a time and manner designated by the Facility, information collected in accordance with this section of this Agreement, to permit Facility to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with the Privacy Rule.

**(g) Survival:**

The Provisions of this Section shall survive the termination of this Agreement.

**5. OBLIGATIONS OF THE FACILITY:**

**(a) Notice of Privacy Practices:**

Facility agrees to provide Business Associate with the Notice of Privacy Practice that the Facility must post in accordance with the Privacy Rule. Facility also agrees to provide Business Associate with any changes to that Notice.

**(b) Revocation of Authorization to Use/Disclose PHI:**

Facility agrees to provide Business Associate with any changes in, or revocation of, permission by Individual to use or disclose PHI, if such changes affect Business Associate's permitted uses and disclosures.

**(c) Restrictions to Use/Disclose PHI:**

Facility agrees to notify Business Associate of any restriction to the use or disclosure of PHI that Facility has agreed to in accordance with the Privacy Rule.

**(d) Permissible Requests:**

Facility agrees not to request Business Associate to use or disclose PHI in any manner that would not be permissible under the Privacy Rule.

**6. TERM AND TERMINATION:**

**(a) Term**

The Term of this Agreement shall be effective as of 4/1/2003, and shall terminate when all PHI provided by Facility to Business Associate, or created or received by Business Associate on behalf of Facility, is destroyed or returned to Facility, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section.

**(b) Termination For Cause**

Upon Facility's knowledge of a material breach by Business Associate, Facility shall provide an opportunity for Business Associate to cure the breach or end the violation within the time specified by Facility in its notice to Business Associate.

**(c) Judicial or Administrative Proceedings; Exclusion**

Either party may terminate this Agreement, effective immediately, if (i) the other party is named as a defendant in a criminal proceeding for a violation of HIPAA, (ii) a finding or stipulation that the other party has violated any standard or requirement of HIPAA or other security or privacy laws is made in any administrative or civil proceeding in which the party has been joined, or (iii) the other party, or any of its officers, shareholders or management employees has been excluded from the Medicare program.

**(d) Termination Without Cause**

Either party has the right to terminate this agreement without cause upon giving 180 days written notice.

**(e) Effect of Termination**

Facility and Business Associate have mutually determined that (i) returning or destroying the PHI received from Facility, or created or received by Business Associate, its agents and subcontractors, on behalf of Facility (including but not limited to PHI contained in Business Associate's and its agents' and subcontractors' data processing, data storage, and other computer systems), is not feasible; and (ii) Business Associate and its agents and subcontractors shall not be obligated to destroy such PHI. Notwithstanding the termination of this Agreement, Business Associate hereby agrees to extend (and to require its agents and subcontractors to extend) the protections of this Agreement to such PHI and to limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate or its agents and subcontractors maintain such PHI.

**7. MISCELLANEOUS:**

**(a) Regulatory References**

A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended, and for which compliance is required.

**(b) Amendment**

The parties acknowledge that state and federal laws relating to electronic data security and privacy are evolving rapidly and that amendment of the Agreement may be required. The parties agree to take such action as is necessary to implement the standards and requirements of HIPAA, the Privacy Rule and other applicable laws relating to the security or confidentiality of PHI, including adopting any necessary or desirable amendments to the Agreement.

**(c) Rights, Remedies, Obligations, or Liabilities**

Nothing expressed or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Facility, Business Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

**(d) Ambiguity**

The parties agree that any ambiguity in this Agreement shall be resolved in favor of meaning that complies and is consistent with HIPAA and the HIPAA regulations.

**(e) No Waiver**

Failure of either party to exercise a right pursuant to this Agreement for any length of time shall not constitute a waiver of said right.

**(f) Modification**

Modification of the terms of this Agreement shall not be effective or binding upon the parties unless and until such modification is committed to writing and executed by the parties.

**(g) Severability**

Should any provision of the Agreement be found unenforceable, it shall be deemed severable and the balance of the Agreement shall continue in full force and effect as if the unenforceable provision had never been made a part hereof.

**(h) Notices**

All notices and communications required or permitted to be given hereunder shall be sent by certified mail, addressed to the other party at its respective address as shown on the signature page, or at such other address as such party shall from time to time designate in writing to the other party, and shall be effective from the date of mailing.

**(i) Captions**

The captions appearing at the beginning of any paragraph or subparagraph hereof are for the convenience of reference only and shall not define or limit any of the terms or conditions hereof and shall have no independent significance.

**(j) Effect on Compensation**

This Agreement is being executed in order to comply with the Health Insurance Portability and Accountability Act and does not impact compensation agreements between the parties. If this Agreement is terminated either with or without cause, Facility will remain responsible for compensating Business Associate for services rendered.

**(k) Reasonableness Standard**

Whenever any party is required by this Agreement to act or to refrain from acting, such action or restraint shall be interpreted by a standard of commercial reasonableness, to require only those actions or restraints as a reasonable person in the same position would expect.

***IN WITNESS WHEREOF:***

Business Associate and Facility have caused this Agreement to be signed and delivered by their duly authorized representatives, as of the date set forth above.

Business Associate  
**Orthotics & Prosthetics One, Inc.**

Facility  
\_\_\_\_\_

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

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

Print Name: Andrew L. Steele

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

Title: Vice President

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

Address: 527 Park Lane, Suite 200  
Waterloo, Iowa 50702

Address: \_\_\_\_\_  
\_\_\_\_\_