

# BUSINESS ASSOCIATE CONTRACT

**THIS CONTRACT** Is entered into on this \_\_\_\_\_ day of \_\_\_\_\_, 2002, between Prosthetic & Orthotic Group and Business Associate, to be effective on the Effective Date.

## **WITNESSETH:**

WHEREAS, Facility is a corporation organized/incorporated under the law of California which is in the business of providing prosthetic & orthotic services; Business Associate is a \_\_\_\_\_ organized/incorporated under the law of \_\_\_\_\_ (**State**) which is in the business of \_\_\_\_\_; and

WHEREAS, the parties have a prior agreement dated \_\_\_\_\_ (the "Prior Agreement") pursuant to which the Business Associate has used, received or disclosed information which would meet the definition of Protected Health Information in this Agreement. The parties wish to supplement the Prior Agreement with this Agreement, which will establish the terms and conditions under which the Protected Health Information provided to or created by the Business Associate from or on behalf of Facility will be handled by and between the parties and with any third parties during the term of this Agreement. This Agreement shall govern in the event of any conflict between this Agreement and the Prior Agreement.]

WHEREAS, Facility will make available and/or transfer to Business Associate certain information, in conjunction with 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 Contract 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 Associates**. "Business Associate" shall mean \_\_\_\_\_ (**Business Associate name**).

(b) **Facility**. "Facility" shall mean Prosthetic & Orthotic Group.

(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 or received by Business Associate from or on behalf of Covered Entity.

(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 CONTRACT.**

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

3. **GENERAL USE AND DISCLOSURE:**

Except as otherwise limited in the Contract, Business Associate shall be permitted to use and/or disclose Protected Health Information on behalf of, or to provide services to, Facility for the purposes described in Exhibit A (individually and collectively the “Services”), if such use or disclosure of Protected Health Information would not violate the Privacy Rule if done by Facility.

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

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

Business Associate agrees to not use or further disclose Protected Health Information provided or made available by Facility other than as permitted or required by the Contract or as required by Law.

***b) Appropriate Safeguards:***

Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information, other than as provided for by this Contract.

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

Business Associate hereby agrees that it shall promptly report to Facility any use or disclosure of Protected Health Information not provided for or allowed by this Contract.

***d) Mitigation Procedures:***

Business Associate agrees to mitigate, to the maximum extent practicable, any harmful effect that is known to the Business Associate from the use or disclosure of Protected Health Information by the Business Associate in violation of the requirements of this Contract.

***e) Subcontractors And Agents:***

Business Associate hereby agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information 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 Contract to Business Associate with respect to such information.

Further, Business Associate shall require subcontractors or agents that receive or have access to PHI to sign an agreement with Business Associate containing substantially the same provisions as this Addendum (the “Subcontractor Agreement”) and further identifying Facility as a third party beneficiary with rights of enforcement and indemnification from such subcontractors or agents in the event of any violation of the Subcontractor Agreement with the Business Agent.”

**f) Right Of Access To Information:**

Business Associate hereby agrees to provide access, at the request of the Facility, and in the time and manner as negotiated by the Facility and Business Associate, to Protected Health Information in a Designated Record Set (as that term is defined in 45 CFR 164.501 of the Privacy Rule, to Facility or, as directed by the Facility, to an individual, in order to meet the requirements under the Privacy Rule.

**g) Amendment And Incorporation Of Amendments:**

Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Facility directs or agrees to pursuant to the Privacy Rule at the request of the Facility or an individual, and in the time or manner designated as negotiated by the Facility and Business Associate.

**h) Access To Books And Records:**

Business Associate hereby agrees to make its internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use or disclosure of Protected Health Information 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 as 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.

**i) Provide Accounting:**

(i) Business Associate agrees to document such disclosures of Protected Health Information 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 Protected Health Information in accordance with the Privacy Rule.

(ii) Business Associate agrees to provide to Facility or an Individual, in a time and manner as negotiated by the Facility and Business Associate, Information collected in accordance with this section of this Contract, to permit Facility to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with the Privacy Rule.

**j) 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 notify Business Associate of any limitations in its Notice of Privacy Practice to the extent that such limitations may affect Business Associate's use or disclosure of Protected Health Information.

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

Facility agrees to notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, 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 Protected Health Information that Facility has agreed to in accordance with the Privacy Rule to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

**d) Permissible Requests:**

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

**6. TERM AND TERMINATION:**

**a) Term:**

The Term of this Contract shall commence on \_\_\_\_\_ and shall terminate i) with respect to the services being provided by Business Associate and the compensation provisions, as of \_\_\_\_\_; and ii) with respect to the obligations of the Business Associate concerning PHI, when all of the Protected Health Information 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 all Protected Health Information, 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 either: 1) provide an opportunity for Business Associate to cure the breach or 2) immediately terminate this Agreement without further notice if Business Associate does not cure the breach or end the violation within the time specified by Facility or 3) if neither termination or cure are feasible, Facility will report the violation to the Secretary.

**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:**

i) Except as provided in paragraph ii) below, upon termination of this Contract, for any reason, Business Associate hereby agrees to return or destroy all Protected Health Information received from Facility, or created or received by Business Associate on behalf of Facility. This provision shall also apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate agrees not to retain any copies of Protected Health Information after termination of this Contract.

ii) In the event that Business Associate determines that return or destruction of Protected Health Information is not feasible, Business Associate shall provide to Facility notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is not feasible, Business Associate agrees to extend the protections of this Contract to such Protected Health Information and limit any further use or disclosure to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains the information.

7. **MISCELLANEOUS:**

**a) Audits, Inspection and Enforcement:**

Facility has the right, with notice and at its expense, to inspect the facilities, systems, books and records of Business Associate to monitor compliance with this Addendum. Business Associate shall promptly remedy any violation of any term of this Addendum. Facility's exercise or non-exercise of this right to audit does not relieve Business Associate of its responsibility to comply with this Addendum.

**b) Insurance:**

Business Associate shall carry such insurance with such insurance companies and in such amounts as are customary for companies providing similar services, and shall name Facility as an additional named insured.

**c) Disclaimer:**

Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

**d) Certification:**

Facility or its authorized agents or contractors, may, at its expense, examine Business Associate's facilities, systems, procedures and records as may be necessary for such agents or contractors to certify to Facility the extent to which Business Associate's security safeguards comply with HIPAA, the Privacy Rule or this Addendum.

**e) Amendment:**

i). Amendment to Comply with Law. The parties acknowledge that state and federal laws relating to electronic data security and privacy are evolving rapidly and that amendment of this 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 this Agreement. The parties understand and agree that Facility must receive satisfactory written assurance from Business Associate that Business Associate will adequately safeguard all PHI that it receives or creates pursuant to this Agreement. Either party may terminate this Agreement upon [30] days written notice in the event the parties are unable to amend this Agreement in a manner that Facility reasonably believes is necessary under HIPAA.

ii) Amendment of Exhibit A. Exhibit A may be modified or amended by mutual agreement of the parties at any time without amendment of this Agreement.

**f) Assistance in Litigation or Administrative Proceedings:**

Business Associate shall make itself, and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under this Agreement, available to Facility, at no cost to Facility, to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against Facility, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA Regulations or other laws relating to security and privacy, except where Associate or its subcontractor, employee or agent is a named adverse party.

**g) No Third Party Beneficiaries:**

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

**h) Effect on Agreement:**

Except as specifically required to implement the purposes of this Addendum, or to the extent inconsistent with this Addendum, all other terms of the Agreement shall remain in force and effect.

**i) Interpretation:**

This Addendum and the Agreement shall be interpreted as broadly as necessary to implement and comply with HIPAA, HIPAA Regulations and applicable state laws.

**j) Indemnity:**

Each party will indemnify, hold harmless and defend the other party to this Agreement from and against any and all claims, losses, liabilities, costs and other expenses incurred as a result of, or arising directly or indirectly out of or in connection with: (i) any misrepresentation, breach of warranty or non-fulfillment of any undertaking on the part of the party under this Agreement; and (ii) any claims, demands, awards, judgments, actions and proceedings made by any person or organization arising out of or in any way connected with the party's performance under this Agreement.

**k) Ambiguity:**

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

**l) Rights and Property:**

All title to the physical records, charts and other Protected Health Information shall remain the sole property of Facility.

**m) 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.

**n) 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 hereto.

**o) No Assignability:**

This is a contract for personal services, and it is the intent of the Facility to have the services performed by the Business Associate. No right or responsibility of either party shall be assigned except upon the prior written consent of the other party hereto.

**p) Binding Effect.:**

This Agreement shall be binding upon the parties hereto, and their respective legal representatives, trustees, receivers, successors and permitted assigns.

**q) Severability:**

Should any provision of this 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.

**r) Governing Law:**

This Agreement and the rights and obligations of the parties hereunder shall in all respects be governed by, and construed in accordance with, the laws of the State of [ insert ], including all matters of construction, validity and performance.

**s) 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.

**t) 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.

**u) Construction.**

The parties acknowledge that they have had the opportunity to be represented by counsel in the negotiation and execution of this Agreement and therefore, it is expressly agreed and in the case of any vagueness or ambiguity with regard to any provision of this Agreement, there shall be no presumption of construction against the drafter of such provision but instead, this Agreement shall be interpreted in accordance with a fair construction of the law.

**v) Entire Agreement:**

This Agreement, including such portions as are incorporated by reference herein, constitutes the entire agreement by, between and among the parties, and such parties acknowledge by their signatures hereto that they do not rely upon any representations or undertakings by any person or party, past or future, not expressly set forth in writing herein.

**w) Representation and Warranty.**

The parties warrant that

- (i) The execution of this Agreement has been duly authorized by their respective Board of Directors and that the representative executing this Agreement is authorized to do so.
- (ii) Neither the party, nor any of its officers, principal owners or managing employees are or have been excluded from participation in the Medicare program, the Medicaid program of any State, or any other state or federal health care program.
- (iii) The Business Associate is not currently under investigation by any regulatory body or the state or federal government in connection with any matter concerning Medicare, Medicaid or any other state or federal health care program.

**x) 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 Contract to be signed and delivered by their duly authorized representatives, as of the date set forth above.

Business Associate  
By: \_\_\_\_\_

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

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

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

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

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

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

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



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**EXHIBIT A**

**PERMITTED USES AND DISCLOSURES**

This Exhibit sets forth the permitted uses and disclosures of Protected Health Information by Business Associate pursuant to Section 2 of the Addendum to the Agreement by and between Facility and Business Associate, dated \_\_\_\_\_, and is effective as of April 14, 2003 (the "Exhibit Effective Date"). This Exhibit may be amended from time to time as provided in Section 5(b) of the Addendum.

1. Purpose(s) of Disclosure. The purpose(s) for which Facility shall disclose Information to Associate are as follows: \_\_\_\_\_  
\_\_\_\_\_

2. Information to be Disclosed. Facility shall disclose the following Information to Business Associate in accordance with the terms of the Agreement: \_\_\_\_\_  
\_\_\_\_\_

3. Permitted Uses and Disclosures of Information. Business Associate shall be limited to the following uses and/or disclosures of Facility's PHI: \_\_\_\_\_  
\_\_\_\_\_

4. Subcontractor(s). If Business Associate intends to utilize any subcontractors) in performing Business Associate's obligations under the Agreement, such subcontractors) shall be identified as follows: \_\_\_\_\_  
\_\_\_\_\_