

# **AccessOne<sup>®</sup>, the Centocor Ortho Biotech Inc. Support System HIPAA Business Associate Contract**

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and its implementing regulations in 45 CFR Parts 160 and 164 (the “Privacy and Security Rules”), contain requirements for maintaining the privacy and security of a person’s protected health information. For purposes of this Agreement, the terms “Protected Health Information” or “PHI” and “Electronic Protected Health Information” or “EPHI” shall have the same meaning as such terms are defined in 45 CFR § 160.103, but limited to such information created, received, maintained, or transmitted by Company in its capacity as a Business Associate of Covered Entity (each as defined below).

The Lash Group, Inc. and TheraCom, LLC, the administrators of the AccessOne<sup>®</sup> Program, meet the definition of a “Business Associate”, as defined in 45 CFR § 160.103 and the associated “Guidance Explaining Significant Aspects of the Privacy Rule” issued by the Department of Health and Human Services (“HHS”), by providing services to or on behalf of the Covered Entity listed below (“Covered Entity”). Centocor Ortho Biotech will not meet the definition of a Business Associate because PHI will not be provided to Centocor Ortho Biotech; except that, in the event that either The Lash Group, Inc., or TheraCom, LLC, no longer provides Business Associate services as set forth herein, Centocor Ortho Biotech may assume Business Associate responsibilities during any resulting transition to a new replacement Business Associate. The Lash Group, Inc., TheraCom, LLC, and Centocor Ortho Biotech shall each be referenced individually as “Company” to the extent that each meets the definition of a Business Associate. Covered Entity and Company agree to the following terms and conditions concerning PHI disclosed to Company by Covered Entity (this “Agreement”).

Capitalized terms used but not otherwise defined shall have the same meaning as those terms in 45 CFR §§ 160.103, 164.304 and 164.501, as such regulations are drafted and may be subsequently updated, amended, or revised. Notwithstanding anything to the contrary in this Agreement, the term “Company” shall refer to each Company separately, and shall not create any joint liability between the Companies. No Company shall be required to perform any obligations under this Agreement except with respect to PHI held by that Company, and no Company shall be responsible for the obligations, acts or omissions of another Company, and nor shall any Company be acting in a subcontractor or Business Associate capacity to any other Company under this Agreement.

## **I. Permitted Uses and Disclosures of PHI by Company**

- A. Except as otherwise limited in this Agreement, Company may use or disclose PHI as necessary for the purpose of providing services to Covered Entity associated with administering the AccessOne<sup>®</sup> Program (the “Program”), including but not limited to providing benefits investigations, alternate coverage research and research for prior authorization processes or administrative denial processes, location assistance for infusion sites (as appropriate), personalized care coordination (including benefits explanation to your patients), and patient education materials (providing disease state information and drug administration education); provided that such use or disclosure would not violate the Privacy and Security Rules if done by Covered Entity.
- B. Except as otherwise limited in this Agreement, Company may use or disclose PHI for the proper management and administration of Company provided that in the cases of disclosures: (1) such disclosures are Required By Law; or (2) Company obtains reasonable assurances from the entity to which the PHI is disclosed that: (a) the PHI will remain confidential and will be used or further disclosed only as Required By Law or for the purpose for which Company disclosed PHI to the entity; and (b) the entity will notify Company of any instances of which it is aware in which the confidentiality of the PHI has been breached.
- C. Company may use and disclose PHI to report violations of law to appropriate federal and state authorities, consistent with 45 CFR § 164.502(j)(1).
- D. Company may de-identify the PHI in accordance with 45 CFR § 164.514(b) and use and disclose the de-identified information for any purpose permitted by law.

## **II. Obligations of Company**

- A. Company agrees not to use or further disclose PHI other than as permitted by this Agreement or as permitted by law, including without limitation the Privacy and Security Rules.
- B. Company agrees to implement administrative, physical, and technical safeguards that reasonably and appropriately protect the

confidentiality of PHI, and the confidentiality, integrity, and availability of EPHI in accordance with the Privacy and Security Rules and this Agreement.

- C. Company agrees to report to Covered Entity any Security Incident involving EPHI or other use or disclosure of PHI of which it becomes aware that is not provided for by this Agreement (provided, however, that trivial attempts to penetrate Company's systems that occur on a daily basis, such as scans, "pings," or other unsuccessful attempts to penetrate computer networks or systems maintained by Company, will not be reported).
- D. In the event that Company provides PHI to any agent or subcontractor to whom Company delegates the performance of services for Covered Entity, Company agrees to ensure that any such agent or subcontractor agrees to the same restrictions and conditions that apply through this Agreement to Company with respect to such PHI.
- E. Upon written request from Covered Entity, Company agrees to provide Covered Entity with access to PHI contained in Designated Record Sets held by Company, if any, in order to allow Covered Entity to respond to an individual's request to access and/or copy PHI.
- F. Company agrees to amend PHI contained in Designated Record Sets held by Company, if any, as directed in writing by Covered Entity in accordance with 45 CFR § 164.526.
- G. Company agrees to document disclosures of PHI by Company to any third party that are required to be accounted for under 45 CFR § 164.528, and provide such documentation to Covered Entity upon written request, as necessary to enable Covered Entity to respond to an individual's request for an account of disclosures of PHI under 45 CFR § 164.528.
- H. To assist the Department of Health and Human Services ("HHS") in determining Covered Entity's compliance with the Privacy and Security Rules, Company agrees to make available their internal practices, books, and records relating to the use and disclosure of PHI received from, or created, or received by Company on behalf of Covered Entity, at Company's offices during regular business hours, to Covered Entity or to HHS, after reasonable notice and subject to applicable legal privileges.

### **III. Obligations of Covered Entity**

- A. Covered Entity will notify Company of any limitation in their notice of privacy practices, to the extent that such limitation may affect Company's use or disclosure of PHI.
- B. Covered Entity will notify Company of any changes in, or revocation of, permission by an individual to use or disclose PHI, to the extent that such changes may affect Company's use or disclosure of PHI.
- C. Covered Entity will notify Company of any restriction on the use or disclosure of PHI to which Covered Entity has agreed, to the extent that such restriction may affect Company's use or disclosure of PHI.
- D. Covered Entity shall not request Company to use or disclose PHI in any manner that would not be permissible under the Privacy and Security Rules if done by Covered Entity (except as permitted by Section I.B).
- E. Notwithstanding anything to the contrary in Section III.A-D, Covered Entity shall not agree to any limitations or restrictions on the use or disclosure of PHI that may affect Company's ability or cost to provide its services without the prior agreement of Company.

### **IV. Term and Termination**

- A. Each party's obligations under this Agreement will remain in effect for as long as Company provides services to Covered Entity that require the use or disclosure of PHI. The provisions of Sections IV.C and V survive the expiration or termination of this Agreement for any reason.
- B. If Covered Entity learns of a material breach of this Agreement by Company, Covered Entity shall provide an opportunity for Company to cure the breach or end the violation. If Company fails to cure the breach or end the violation within a reasonable amount of time, but no less than thirty (30) calendar days, Covered Entity may terminate this Agreement and any services being provided to Covered Entity by Company that require the use or disclosure of PHI. If the parties agree that it is not possible to cure the breach, Covered Entity may immediately terminate the services being provided to Covered Entity by Company that require the use or disclosure of PHI. If neither termination nor cure is feasible, Covered Entity shall report the violation to HHS.

C. Upon termination of this Agreement for any reason, Company will return or destroy all PHI received from Covered Entity if it is commercially feasible to do so. However, if it is not commercially feasible to return or destroy the PHI, Company will notify Covered Entity of the conditions that make return or destruction infeasible and Company will limit further uses and disclosures of the PHI to those purposes for as long as Company maintains the PHI.

## V. Miscellaneous

- A. This Agreement constitutes the entire agreement among the parties with respect to the protection of PHI disclosed by Covered Entity to Company in the course of Company administering the Program. This Agreement supersedes all prior arrangements and understandings between Company and Covered Entity with respect to the matters addressed herein. The terms of any other agreement related to the protection of PHI disclosed by Covered Entity to Company shall not amend, supplement, or modify this Agreement. Any modification of this Agreement must be in writing and signed by authorized representatives of the parties.
- B. The parties agree to enter into good faith negotiations to modify this Agreement to the extent necessary to make it consistent with any new or revised laws, regulations, or judicial decisions governing the use or disclosure of PHI.
- C. Nothing in this Agreement is intended to confer any rights or obligations on any person other than the parties and their respective successors and assigns.
- D. The parties will make good faith efforts to resolve informally any disputes under this Agreement. No party will be liable to another party for any incidental, consequential, special, or punitive damages with respect to the matters addressed in this Agreement.
- E. All notices, requests, and demands or other communications to be given under this Agreement to a party shall be made by (1) first class mail, registered or certified, (2) overnight courier to such party's address given below, and/or (3) by facsimile to the facsimile number listed below, or to such other address or facsimile number as that party shall designate in writing to the other party.
- F. This Agreement shall be governed by and interpreted in accordance with the laws of Delaware, without regard to its conflict of laws principles.
- G. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together will constitute one and the same agreement. Facsimile copies shall be deemed to be originals.

### "Covered Entity"

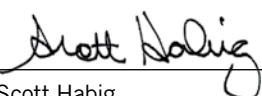
By: \_\_\_\_\_ Name: \_\_\_\_\_  
Title: \_\_\_\_\_ Date: \_\_\_\_\_  
Organization: \_\_\_\_\_  
Address: \_\_\_\_\_  
Phone: \_\_\_\_\_ Fax: \_\_\_\_\_


### "Company"


Centocor Ortho Biotech Inc.  
800 Ridgeview Drive  
Horsham, PA 19044

The Lash Group, Inc.  
3735 Glen Lake Drive  
Charlotte, NC 28208

TheraCom, LLC  
9717 Key West Avenue  
Rockville, MD 20850

By:   
Name: Scott Habig  
Title: Vice President  
Date: \_\_\_\_\_

By:   
Name: Honora Gabriel  
Title: Director  
Date: \_\_\_\_\_

By:   
Name: Mark Spotts  
Title: Vice President  
Date: \_\_\_\_\_

**Fax completed form to 1-866-489-5955 or mail to AccessOne®, P.O. Box 220829, Charlotte, NC 28222-0829.  
For additional information, call 1-888-ACCESS-1 (222-3771).**

**Centocor Ortho Biotech Proprietary**