

Siliq Solutions™ HIPAA Business Associate Agreement

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and its implementing regulations in 45 CFR Parts 160 and 164 as amended from time to time, including by the Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), collectively, 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 term Protected Health Information (“PHI”) shall include Electronic Protected Health Information (“EPHI”) each as defined in the HIPAA regulations, and each shall have the same meaning as such terms are defined in 45 CFR § 160.103, but limited to such information that is created, received, maintained, or transmitted by Company in its capacity as a Business Associate of Covered Entity (each as defined below).

The Lash Group, LLC (“Lash Group”), administrators of Siliq Solutions, and Valeant Pharmaceuticals (“Valeant”), may meet the definition of a “Business Associate,” as defined in 45 CFR § 160.103 issued by the Department of Health and Human Services (“HHS”), by receiving PHI from or receiving, creating, maintaining or transmitting PHI on behalf of the Covered Entity listed below (“Covered Entity”). Valeant will not be deemed to be Company or to meet the definition of a Business Associate except in the event that Lash Group no longer provides Business Associate services as set forth herein and Valeant receives PHI from or creates, receives, transmits or maintains PHI on behalf of Covered Entity and assumes responsibilities for operating Siliq Solutions during any resulting transition to a new replacement program administrator, provided that Valeant shall not be deemed to be Company or to meet the definition of a Business Associate as a result of receiving PHI as described in Section 1.A for the provision of program management services pursuant to an authorization collected from the applicable patient by Covered Entity pursuant to Section III.E, by Lash Group or through any other appropriate manner. Lash Group and/or Valeant, as applicable, 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 the Privacy and Security Rules, as such rules are drafted and may be subsequently updated, amended, or revised, and as of the applicable compliance date of such changes. 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 Lash Group and Valeant. No Company shall be required to perform any obligations under this Agreement except with respect to PHI held by that Company, and neither Lash Group nor Valeant shall be responsible for the obligations, acts, or omissions of the other, and nor shall either be acting in a Subcontractor or Business Associate capacity to the other under this Agreement.

I. Permitted Uses and Disclosures 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 Siliq Solutions (“the Program”), including but not limited to providing benefits investigation, alternate coverage research and research for prior authorization processes or administrative denial processes, personalized care coordination between sites of service (as appropriate) and other health care providers (such as specialty pharmacies), personalized patient assistance (including benefits explanation and cost support, if applicable), providing provider and patient education materials (including health care updates relevant to site of care, disease state information and drug administration education), and any other services required to support Covered Entity’s patients access to Program-related product prescribed by Covered Entity; provided that such use or disclosure would not violate the Privacy and Security Rules if done by Covered Entity except as permitted by 45 CFR 164.504(e). Without limiting the foregoing, the care coordination services provided by the Company with respect to Covered Entity’s patients may include disclosing PHI to Siliq Solutions program management, which may include program managers from Lash Group and Valeant, as well as Field Reimbursement Managers (FRMs) employed by Valeant, to facilitate provider and patient access to Siliq Solutions support services. Care coordination services provided by the Company with respect to Covered Entity’s patients may also include disclosing PHI to the specialty pharmacies used by such patients, or the business associate of the relevant specialty pharmacy to confirm with the relevant specialty pharmacy that the medication order has been fulfilled.
- B. Company may use or disclose PHI for the proper management and administration of Company or to fulfill Company’s legal responsibilities, provided that in the cases of such 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 for public health, health oversight and for other purposes permitted by and consistent with 45 CFR §164.512 or 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 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 or required by this Agreement or as Required by Law, including without limitation the Privacy and Security Rules. Company agrees to comply with the requirements of the Privacy and Security Rules that are directly applicable to Business Associates.

- B. Company agrees to use appropriate safeguards and comply, where applicable, with Subpart C of 45 CFR Part 164 with respect to EPHI, to prevent the use or disclosure of PHI other than as provided in this Agreement.
- C. Company agrees to report to Covered Entity any Security Incident of which it becomes aware or any use or disclosure of PHI of which it becomes aware that is not provided for by this Agreement. The parties acknowledge that the Company experiences Unsuccessful Security Incidents (as defined below) and agree that this Section constitutes notice by the Company and satisfies any reporting required of the ongoing existence or occurrence of attempted but Unsuccessful Security Incidents for which no additional notification shall be required. "Unsuccessful Security Incidents" shall include but are not limited to activity such as "pings" and other broadcast attacks on Company's firewall, port scans, unsuccessful log-on attempts, denials of service, any combination of the above, and any other activities that do not result in unauthorized access, use or disclosure of EPHI.
- D. In the event that Company provides PHI to any Subcontractor to whom Company delegates the performance of services for Covered Entity, Company agrees to ensure that any such 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. Company also agrees, upon Covered Entity's written request, to respond directly to an Individual's request for EPHI in a Designated Record Set in electronic format and to send such EPHI to another person as directed by the Individual to the extent required by and in accordance with 45 CFR § 164.524.
- 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 HHS in determining Covered Entity's compliance with the Privacy Rule, Company agrees to make available to HHS its 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, after reasonable written notice, and during regular business hours, subject to applicable legal privileges.
- I. Upon discovery by Company of a Breach involving Unsecured PHI, Company shall notify Covered Entity in writing without unreasonable delay, and in no event longer than thirty (30) calendar days following discovery of such Breach. Such notice shall include, to the extent possible, the identification of each Individual whose Unsecured PHI has been, or is reasonably believed to have been accessed, acquired, used or disclosed, and any other available information that Covered Entity is required to include in its notification to the Individual under 45 CFR § 164.404(c).
- J. To the extent Company agrees to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, Company agrees to comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligations.

III. Obligations of Covered Entity

- A. Covered Entity will notify Company of any limitation in its 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.
- E. Notwithstanding anything to the contrary in Section III.A-D, Covered Entity shall be responsible for obtaining all authorizations or permissions required for Company to provide its services as described in Section I.A in accordance with all applicable laws, including HIPAA, and shall not agree to any limitations or restrictions on the use or disclosure of PHI otherwise permitted or required by this Agreement without the prior written 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 involve the creation, receipt, transmission or maintenance 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.

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 may retain such PHI and will limit further uses and disclosures of the PHI to those purposes that make return or destruction infeasible for as long as Company maintains the PHI. This provision shall apply to PHI that is in the possession of the Company and/or its Subcontractors. Company will require its Subcontractors to extend the same protections to PHI in their possession.

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. Any modification of this Agreement must be in writing and signed by authorized representatives of the parties.
- B. The parties agree to enter into 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 reasonable efforts to resolve informally any disputes under this Agreement. NO PARTY WILL BE LIABLE TO ANOTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES WITH RESPECT TO THE MATTERS ADDRESSED IN THIS AGREEMENT, REGARDLESS OF THE CAUSE OR LEGAL THEORY AND WHETHER OR NOT FORESEEABLE.
- 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 or personal delivery 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, except to extent preempted by the Privacy and Security Rules.
- 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”

Signed by: _____ Name: _____

Title: _____ Date: _____

Organization: _____

Address: _____

Phone: _____ Fax: _____

“Company”

Valeant Pharmaceuticals
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807

The Lash Group, LLC
1800 Innovation Point
Fort Mill, SC 29175

Signed by: 

Signed by: 

Name: Brian O'Neill

Name: Trish Walters

Title: Vice President, Strategic Pricing, Contracting & Reimbursement

Title: Senior Program Manager, Operations

Date: _____

Date: _____

Fax completed form to 877-204-3888 or mail to Siliq Solutions, P.O. Box 220761, Charlotte, NC 28222-0761.

For additional information, call 855-RX-SILIQ (855-797-4547).