

## **BUSINESS ASSOCIATE AGREEMENT**

THIS BUSINESS ASSOCIATE AGREEMENT (this “Agreement”) is made as of the \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, by and between **DrugPak, LLC** (“Business Associate”) and \_\_\_\_\_ (“Covered Entity”).

### **R E C I T A L S :**

WHEREAS Covered Entity and Business Associate have entered into an agreement or agreements, pursuant to which Business Associate provides certain services to Covered Entity (individually or collectively, the “Services Agreement”), pursuant to which Business Associate may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), including all pertinent regulations issued by the U.S. Department of Health and Human Services (45 C.F.R. Parts 160 and 164), as amended by the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (collectively, “HIPAA Law”);

WHEREAS to carry out its obligations under the Services Agreement, Business Associate may create, maintain, transmit, or receive, on behalf of Covered Entity, Individually Identifiable Health Information, as such term is defined in 45 C.F.R. Part 160 and Subparts A and E of Part 164 (the “Privacy Rule”);

WHEREAS the Privacy Rule and 45 C.F.R. Parts 160 and Subparts A and C of Part 164 (the “Security Rule”) obligate Covered Entity to enter into a contract with Business Associate to ensure that Business Associate appropriately safeguards such information; and

WHEREAS Covered Entity and Business Associate desire to enter into this Agreement in addition to the Services Agreement in order to enable Covered Entity to satisfy its obligations under the HIPAA Law.

**NOW, THEREFORE**, for and in consideration of the mutual promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

### **I. DEFINITIONS**

1.1 “Breach” shall have the same meaning as the term “breach” in 45 C.F.R. Part 164, Subpart D (the “Breach Notification Rule”).

1.2 “Data Aggregation” shall have the same meaning as the term “data aggregation” in the Privacy Rule.

1.3 “Designated Record Set” shall have the same meaning as the term “designated record set” in the Privacy Rule.

1.4 “Disclosure” shall have the same meaning as the term “disclosure” in the Privacy Rule.

1.5 “Discovery” shall have the same meaning as the term “discovery” in 45 C.F.R. § 164.410(a)(2).

1.6 “Electronic Protected Health Information” shall have the same meaning as the term “electronic protected health information” in the Security Rule.

1.7 “Health Care Operations” shall have the same meaning as the term “health care operations” in the Privacy Rule.

1.8 “Individual” shall have the same meaning as the term “individual” in the Privacy Rule and shall include a person who qualifies as a personal representative in accordance with the Privacy Rule.

1.9 “Minimum Necessary” shall have the same meaning as the term “minimum necessary” in the Privacy Rule.

1.10 “Notice of Privacy Practices” shall have the same meaning as the term “notice of privacy practices” in the Privacy Rule.

1.11 “Protected Health Information” or “PHI” shall have the same meaning as the term “protected health information” in the Privacy Rule, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

1.12 “Required by Law” shall have the same meaning as the term “required by law” in the Privacy Rule.

1.13 “Secretary” shall mean the Secretary of the United States Department of Health and Human Services (“HHS”).

1.14 “Security Incident” shall have the same meaning as the term “security incident” in the Security Rule.

1.15 “Transaction” shall have the same meaning as the term “transaction” in 45 C.F.R. Parts 160 and 162 (the “Transactions Rule”).

1.16 “Unsecured Protected Health Information” shall have the same meaning as the term “unsecured protected health information” in the Breach Notification Rule.

## **II. OBLIGATIONS OF BUSINESS ASSOCIATE**

2.1 **Confidentiality.** Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by this Agreement or as Required by Law.

2.2 **Safeguards.** Business Associate agrees to use appropriate safeguards and comply, where applicable, with the Security Rule with respect to Electronic Protected Health Information, to prevent the use or disclosure of the Protected Health Information other than as provided for by this Agreement.

2.3 **Mitigation.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.

2.4 **Reporting.** Business Associate agrees to promptly report to Covered Entity any use or disclosure of Protected Health Information not provided for by this Agreement of which it becomes aware, including any Breach of Unsecured Protected Health Information as required by 45 C.F.R. § 164.410.

2.5 Agents and Subcontractors. Business Associate agrees to ensure, in accordance with 45 C.F.R. § 164.502(e)(1)(ii), that any agents, including without limitation subcontractors, that create, receive, maintain or transmit protected health information on behalf of Business Associate agree to the same restrictions and conditions that apply to Business Associate with respect to such information.

2.6 Access and Amendment. Business Associate agrees to provide access, within five (5) days of receiving a written request from Covered Entity, to Protected Health Information in a Designated Record Set to Covered Entity or, as directed by Covered Entity, to an Individual, in order to meet the requirements under 45 C.F.R. § 164.524. Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 C.F.R. § 164.526 within five (5) days of receiving written notice from Covered Entity. In the event an Individual requests such access or amendment directly from Business Associate, Business Associate shall promptly forward such request to Covered Entity within five (5) days.

2.7 Performing Obligations of Covered Entity. To the extent that Business Associate is to carry out any obligation of Covered Entity under the Privacy Rule, Business Associate agrees to comply with the requirements of the Privacy Rule that apply to Covered Entity in the performance of such obligation.

2.8 Books and Records. Business Associate agrees to make its internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information available to (i) Covered Entity, upon written request, and (ii) the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's and/or Business Associate's compliance with the Privacy Rule. If the Secretary requests such access, Business Associate shall promptly notify Covered Entity and shall consult and cooperate with Covered Entity concerning the proper response to such request. Notwithstanding the foregoing, nothing in this section shall impose upon Covered Entity any obligation to review Business Associate's practices, books or records.

2.9 Accounting. Business Associate agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528. Business Associate agrees to provide to Covered Entity, within fifteen (15) days of receiving a written request from Covered Entity, information collected in accordance with this section to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528. In the event an Individual requests an accounting of disclosures of Protected Health Information directly from Business Associate, Business Associate will forward such request to Covered Entity within five (5) days.

2.10 Uses and Disclosures Required by Law. Except to the extent prohibited by law, Business Associate shall immediately notify Covered Entity if it receives a request for disclosure of Protected Health Information with which Business Associate believes it is Required by Law to comply and disclose pursuant to which would not otherwise be permitted by this Agreement. Business Associate shall provide Covered Entity with a copy of such request, shall consult and cooperate with Covered Entity concerning the proper response to such request.

2.11 Electronic Protected Health Information. With regard to Protected Health Information which is Electronic Protected Health Information (as defined in the Security Rule), Business Associate shall: (i) comply with the applicable requirements of the Security Rule and develop, document, implement, maintain, and use administrative, physical, and technical safeguards that reasonably and appropriately

protect the confidentiality, integrity, and availability of such information; (ii) in accordance with 45 C.F.R. § 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit Electronic Protected Health Information on behalf of Business Associate agree to comply with the applicable requirement of the Security Rule by entering into a contract or other arrangement that complies with 45 C.F.R. § 164.314; and (iii) report to Covered Entity any Security Incident of which Business Associate becomes aware, including any Breach of Unsecured Protected Health Information as required by 45 C.F.R. § 164.410. Business Associate's obligations under this Section are in addition to its other obligations set forth in Section 2 of this Agreement.

## 2.12 Reporting.

(a) Within two (2) business days of Discovery, Business Associate will report to Covered Entity any use or disclosure of Covered Entity's PHI that is not permitted by this Agreement. Without unreasonable delay, and in any event no later than five (5) days after Discovery, Business Associate shall provide Covered Entity with written notification that includes: (i) a description of the Breach, (ii) to the extent possible, the identification of each Individual whose Protected Health Information has been, or is reasonably believed by Business Associate to have been, accessed, acquired, used or disclosed during the Breach, and (iii) any other available information that Covered Entity is required to include in notifications to Individuals under 45 C.F.R. § 164.404(c) at the time of the written notification or promptly thereafter as information becomes available. Further, Business Associate will provide Covered Entity any additional information required under the HITECH Act and its implementing regulations, as amended from time to time.

(b) Immediately following Discovery, but in no event later than two (2) business days, Business Associate will report to Covered Entity any suspected or actual Breach of Unsecured Protected Health Information, any suspected or actual disclosure or inappropriate access of Covered Entity's information, or any Security Incident.

2.13 HITECH Act. Business Associate and Covered Entity agree that to the extent not incorporated or referenced in this Agreement, other requirements under the HITECH Act (as well as any other requirements under HIPAA) that apply to business associates and that are required to be incorporated by reference in a business associate agreement are incorporated into this Agreement as if set forth in this Agreement in their entirety and are effective as of the applicable date for each such requirement on which HHS will require business associates to comply with such requirement. Business Associate shall comply with the obligations of a business associate as prescribed by the HIPAA Law and the HITECH Act, commencing on such applicable date of each such requirement.

## **III. PERMITTED USES AND DISCLOSURES**

3.1 Use or Disclosure to Provide Services Under the Services Agreement. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Services Agreement, provided that such use or disclosure would not violate the Privacy Rule if done by Covered Entity.

3.2 Use or Disclosure for Business Associate's Management and Administration. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information for its proper management and administration or to carry out its legal responsibilities. Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for its proper management and administration, provided that such 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.

3.3 Use or Disclosure to Provide Data Aggregation Services. Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide Data Aggregation services to Covered Entity as permitted by 42 C.F.R. § 164.504(e)(2)(i)(B).

3.4 De-Identification of Protected Health Information. Business Associate may de-identify any and all Protected Health Information provided that de-identification conforms to the requirements of the Privacy Rule. The parties acknowledge and agree that data that is de-identified in accordance with the Privacy Rule is not Protected Health Information under the terms of this Agreement. Business Associate shall not sell any Protected Health Information without the express consent of Covered Entity.

3.5 Minimum Necessary Uses, Disclosures and Requests. Subject to the exceptions described in 45 C.F.R. §164.502(b)(2), Business Associate must make reasonable efforts to limit Protected Health Information to the minimum necessary to accomplish the intended purpose of a use, disclosure or request otherwise permitted by this Agreement, as required by the Privacy Rule.

#### **IV. RESPONSIBILITIES OF COVERED ENTITY**

4.1 Notice of Privacy Practices. Covered Entity shall notify Business Associate of any limitation(s) of which it is aware in the notice of privacy practices of Covered Entity in accordance with 45 C.F.R. § 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of Protected Health Information.

4.2 Change or Revocation of Permission. Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose Protected Health Information of which Covered Entity is aware, to the extent that such changes may affect Business Associate's use or disclosure of Protected Health Information.

4.3 Restrictions on Use or Disclosure. Covered Entity shall notify Business Associate of any restriction, of which Covered Entity is aware, to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of Protected Health Information.

#### **V. IMPERMISSIBLE REQUESTS BY COVERED ENTITY**

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

#### **VI. TERM AND TERMINATION**

6.1 Term. The term of this Agreement shall be effective as of the date of the Services Agreement and shall expire when all of the Protected Health Information is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in Section 6.3 of this Agreement.

6.2 Termination. Upon Covered Entity's knowledge of a material breach or violation of this Agreement by Business Associate, Covered Entity may either: (i) provide an opportunity for Business Associate to cure the breach or end the violation and terminate, without penalty, this Agreement and the Services Agreement if Business Associate does not cure the breach or end the violation within forty-five (45) days of receiving notice of such breach or violation from Covered Entity; (ii) immediately terminate, without penalty, this Agreement and the Services Agreement if Business Associate has breached or violated a material term of this Agreement and Covered Entity reasonably determines that cure is not feasible; or (iii) if Covered Entity reasonably determines neither termination nor cure are feasible, Covered Entity may report the breach or violation to the Secretary.

6.3 Return or Destruction of Protected Health Information Upon Termination.

(a) Except as provided in (b) below, upon termination for any reason of this Agreement, Business Associate shall return or destroy all Protected Health Information, including such information in the possession of subcontractors or agents of Business Associate, and shall certify to Covered Entity in writing and provide satisfactory evidence that Business Associate has fully accomplished the same. Business Associate shall retain no copies of the Protected Health Information.

(b) In the event Business Associate determines that returning or destroying such Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Business Associate shall then extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

## **VII. INDEMNITY**

Business Associate will indemnify and hold harmless Covered Entity and any affiliate, officer, director, employee or agent of Covered Entity from and against any claims, causes of action, losses, liabilities, penalties, demands, costs or expenses, including attorneys' fees and judicial, administrative, arbitration or other proceeding costs, arising out of or in connection with any non-permitted use or disclosure of Covered Entity's Protected Health Information or other breach of this Agreement by Business Associate or any subcontractor or agent of Business Associate. This Section shall survive termination of this Agreement.

## **VIII. MODIFICATIONS TO COMPLY WITH STANDARDS**

Covered Entity and Business Associate agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Law, the HITECH Act, and any other applicable law.

## **IX. MISCELLANEOUS**

8.1 Organizational Representations. Each party represents and warrants to the other party that:

(a) It is duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized or licensed;

(b) It has the full power to enter into this Agreement and to perform its obligations described in this Agreement;

(c) The performance by it of its obligations hereunder have been duly authorized by all necessary corporate or other actions and will not violate any provision of any charter or bylaws or similar organizational or governing document;

(d) Neither the execution of this Agreement by such party nor its performance hereunder will directly or indirectly violate or interfere with the terms of any other agreement to which it is a party or give any governmental entity the right to suspend, terminate or modify any of its governmental authorizations or assets required for its performance;

(e) Its employees, agents, representatives and members of its workforce, whose services may be used to fulfill obligations under this Agreement, are or shall be appropriately informed of the terms of this Agreement and are under legal obligations, by contract or otherwise, sufficient to enable such party to fully comply with all provisions of this Agreement; and

(f) It will reasonably cooperate with the other party in the performance of the mutual obligations under this Agreement.

8.2 Regulatory References. A reference in this Agreement to a section in the Privacy Rule, the Security Rule, the HITECH Act, or any other section promulgated under HIPAA means the section as in effect or as amended.

8.3 Survival. Any provision of this Agreement which by its terms imposes an obligation which continues following termination of this Agreement shall survive the termination of this Agreement and shall continue to be binding on the parties.

8.4 Injunctive Relief. Business Associate understands and acknowledges that any use or disclosure of Protected Health Information in violation of this Agreement will cause Covered Entity irreparable harm, the amount of which may be difficult to ascertain, and therefore agrees that Covered Entity shall have the right to apply to a court of competent jurisdiction for specific performance and/or an order restraining and enjoining any such further use or disclosure and for such other relief as Covered Entity shall deem appropriate. Such right of Covered Entity is to be in addition to the remedies otherwise available to Covered Entity at law or in equity. Business Associate expressly waives the defense that a remedy in damages will be adequate and further waives any requirement in an action for specific performance or injunction for the posting of a bond by Covered Entity.

8.5 Interpretation; Entire Agreement; Amendment; Waiver. The headings of sections in this Agreement are for reference only and shall not affect the meaning of this Agreement. Any ambiguity in this Agreement shall be resolved to permit Covered Entity and Business Associate to comply with HIPAA and/or the HITECH Act. With respect to the subject matter of this Agreement, this Agreement supersedes all previous contracts by and between the parties and, together with the Services Agreement, constitutes the entire agreement between the parties. In the event that a provision of this Agreement conflicts with a provision of the Services Agreement, the provision of this Agreement shall control; provided, however, that to the extent that any provision within the Services Agreement imposes more stringent requirements than that required in the Agreement, the parties agree to adhere to the terms of the Services Agreement. Otherwise, this Agreement shall be construed under, and in accordance with, the terms of the Services Agreement. This Agreement may be amended only by written agreement between the parties. The failure

of either party to enforce at any time any provision of this Agreement shall not be construed as a waiver of such provision, nor in any way affect the validity of this Agreement or the right of either party thereafter to enforce each as every such provision. Waiver of a breach of any provision of this Agreement shall not be deemed a waiver of any other breach of the same or any different provision.

8.6 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 the parties and the respective successors and assigns of the parties any rights, remedies, obligations, or liabilities whatsoever.

8.7 Notices. Any notice required or permitted under this Agreement shall be given in writing and delivered by electronic mail or facsimile with confirmation of receipt, by hand, by nationally recognized overnight delivery service or by registered or certified mail, postage pre-paid and return receipt requested, to the following:

Covered Entity: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Attn: \_\_\_\_\_

Business Associate: DrugPak, LLC  
8001 Conner Rd.  
Powell, Tennessee 37849

Notice of a change in address of one of the parties shall be given in writing to the other party as provided above. All notices shall be effective upon receipt.

8.8 Assignment; Binding Effect. No assignment of the rights or obligations of either party under this Agreement shall be made without the express written consent of the other party, which consent shall not be unreasonably withheld. This Agreement shall be binding upon and shall inure to the benefit of the parties, their respective successors and permitted assignees.

8.9 Severability. If any provision of this Agreement is rendered invalid or unenforceable by the decision of any court, arbitrator or administrative body, such invalid or unenforceable provision shall be severed from this Agreement and all other provisions of this Agreement shall remain in full force and effect.

8.10 Counterparts; Facsimiles. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original. Facsimile and electronic copies hereof shall be deemed to be originals.

[Signature page to follow.]



IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first written above.

**BUSINESS ASSOCIATE:**

**DrugPak, LLC**

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

Name: David Gonçalves

Title: General Manager

**COVERED ENTITY:**

\_\_\_\_\_

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

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

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