

**2023-0000XX**

**Business Associate Agreement**

**THIS BUSINESS ASSOCIATE AGREEMENT** (“Agreement”) is made by, and between \_\_\_\_\_, represented herein by the undersigned authorized individual, having its principal offices located at San Juan, Puerto Rico (“Business Associate”) and The Puerto Rico Health Insurance Administration (“PRHIA”), represented herein by the individual signing below, who is authorized to act for and on behalf of PRHIA and with its principal offices at San Juan, Puerto Rico. PRHIA and Business Associate, collectively, may hereinafter be referred to as the “Parties.”

**WHEREAS**, PRHIA and Business Associate are parties to one or more agreements and/or may in the future become parties to additional agreements (collectively, the “Underlying Agreements”), pursuant to which Business Associate provides certain services to PRHIA and, in connection with such services, creates, receives, uses or discloses for or on behalf of PRHIA certain individually identifiable Protected Health Information relating to patients and/or insured members of health plans with which PRHIA is involved (“PHI”) that is subject to protection under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as amended by the Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B, of the American Recovery and Reinvestment Act of 2009 (“HITECH Act”) and regulations promulgated thereunder, as such law and regulations may be amended from time to time (collectively, “HIPAA”); and

**WHEREAS**, PRHIA and Business Associate wish to comply in all respects with the requirements of HIPAA, including requirements applicable to the relationship between a Covered Entity and its Business Associates;

**THEREFORE**, in consideration of the mutual promises contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties agree as follows:

**Section 1. Definitions.**

- a. “Business Associate” shall have the same meaning given to such term as defined in 45 CFR § 160.103 and, for purposes of this Agreement, shall mean the Business Associate indicated above.

- b. "Covered Entity" shall have the same meaning given to such term as defined in 45 CFR § 160.103 and, for purposes of this Agreement.
- c. "Electronic Protected Health Information" or "e-PHI" shall have the same meaning given to such term as defined in 45 CFR § 160.103 limited to the information created, received, transmitted or maintained by the Business Associate in electronic form format or media.
- d. "Individual" shall have the same meaning given to such term as defined in 45 CFR § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).
- e. "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 respectively.
- f. "Protected Health Information" or "PHI" shall have the same meaning given to such term as defined in 45 CFR § 160.103, limited to the information created, transmitted, maintained, or received by Business Associate from or on behalf of PRHIA.
- g. "Required By Law" shall have the same meaning given to such term as defined in 45 CFR § 164.103 and The Health Information Technology for Economic and Clinical Health Act (HITECH) Division A: Title XIII, Subtitle D.
- h. "Security Rule" shall mean the Standards for Security of Electronic Protected Health Information as specified in 45 C.F.R. Part 160 and subparts A and C of Part 164.
- i. Other definitions: The following terms used in this Agreement shall have the same meaning as those in the Privacy Rule and Security Rule: Breach, Designated Record Set, Disclosure, Notice of Privacy Practices, Secretary, Security Incident, Standard, Subcontractor, Transaction, Unsecured Protected Health Information, and Use. Other terms shall have the definitions set forth in this Agreement.

## **Section 2. Obligations and Activities of Business Associate.**

2.1 Business Associate may not use or disclose Protected Health Information other than as permitted or required by this Agreement, the Underlying Agreements or as Required by Law.

2.2 Business Associate agrees to use appropriate safeguards, including without limitation, administrative, physical and technical safeguards set forth in the Security Rule, to prevent use or Disclosure of the Protected Health Information other than as provided for by this Agreement and to reasonably and appropriately employ the same standards as Required by Law to protect the confidentiality, integrity and

availability of any Electronic Protected Health Information (e-PHI) that it may receive, maintain or transmit on behalf of PRHIA.

2.3 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 Business Associate agrees to report to PRHIA, in writing, within twenty-four (24) hours, any use or disclosure, or suspected use or disclosure, of the Protected Health Information not provided for by this Agreement or any Security Incident resulting in an attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations or acquisition of any PHI, including e-PHI, of which it becomes aware. Business Associate shall report the unauthorized use or disclosure using the notification process specified in the services agreement executed between Business Associate and PRHIA. All reports shall include the information required by the Privacy Rule and Security Rule, to the extent available.

Business Associate hereby reports to PRHIA that incidents including, but not limited to, ping sweeps or other common network reconnaissance techniques, attempts to log on to a system with an invalid password or username, and denial of service attacks that do not result in a server being taken off line, may occur from time to time.

2.5 Business Associate must in accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any Subcontractors, agents or affiliates of the Business Associate, that create, receive, maintain, or transmit PHI on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information. Business Associate must obtain satisfactory assurances in the form of a written agreement or memorandum of understanding directly from Subcontractors stipulating that the Subcontractor agrees to comply with the same restrictions and conditions set forth in this Agreement. Business Associate must ensure that any agent or Subcontractor to whom the Business Associate provides PHI not export PHI beyond the borders of the Commonwealth of Puerto Rico without express written agreement of PRHIA.

2.6 Business Associate agrees to provide access, at the written request of PRHIA, and in the time and manner designated by PRHIA, to Protected Health Information

in a Designated Record Set, to PRHIA or an Individual in order to meet the requirements under 45 CFR §164.524.

2.7 Business Associate agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that PRHIA directs or agrees to pursuant to 45 CFR §164.526 at the written request of PRHIA or an Individual, and in the time and manner designated by PRHIA.

2.8 Business Associate agrees to make available to PRHIA internal practices, books, and records relating to the use and Disclosure of PHI, or at the request of PRHIA, to the Secretary, in a time and manner designated by PRHIA or the Secretary, for purposes of the Secretary determining compliance with the Privacy and Security Rules.

2.9 Business Associate agrees to document such Disclosures of PHI and information related to such Disclosures as would be required for PRHIA to respond to a request by an Individual for an accounting of Disclosures of Protected Health Information in accordance with 45 CFR §164.528.

2.10 Business Associate agrees to provide to PRHIA or an Individual, in time and manner designated by PRHIA, information collected in accordance with Section 2.9 of this Agreement, to permit PRHIA to respond to a request by an Individual for an accounting of Disclosures of Protected Health Information by Business Associate in accordance with 45 CFR §164.528.

2.11 Business Associate understands and agrees that it will not access or use any Protected Health Information of any Individual except for those Individuals whose PHI has been disclosed to Business Associate, or is created, received, maintained, or transmitted by or to Business Associate on behalf of PRHIA, and it will further limit access to that Protected Health Information that is necessary to the activities undertaken by Business Associate on behalf of PRHIA and as otherwise permitted by this Agreement.

2.13 Business Associate will, pursuant to the HITECH Act and its implementing regulations, comply with the requirements of the Privacy Rule, including those contained in 45 CFR §§ 164.502(e) and 164.504(e)(1)(iii). To the extent Business Associate is to carry out one or more of PRHIA's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate agrees to comply with the requirements of Subpart E that apply to PRHIA in the performance of such obligations. Business

Associate will not directly or indirectly receive remuneration in exchange for any Protected Health Information, subject to the exceptions contained in the HITECH Act, without a valid authorization from the applicable Individual. Business Associate will not use Protected Health Information to engage in any communication which might be deemed to be “Marketing” under the HITECH Act without prior written permission from PRHIA and without Individual authorizations, to the extent required by the HITECH Act and its implementing regulations. In addition, Business Associate will, pursuant to the HITECH Act and its implementing regulations, comply with all applicable requirements of the Security Rule.

2.14 Business Associate agrees to make uses of and disclosures and requests for Protected Health Information consistent with HIPAA and any of PRHIA’s Minimum Necessary policies and procedures provided to Business Associate and consistent with PRHIA’s Notice of Privacy Practices. PRHIA asserts that its Minimum Necessary policies and procedures are consistent with 45 C.F.R. §164.514(d) and Business Associate agrees to comply with the provisions of that rule.

2.15 To the extent Business Associate submits Standard Transactions on behalf of PRHIA or assists PRHIA with submission of Standard Transactions, Business Associate shall comply with HIPAA’s Transaction and code set Standards for such Transactions and will provide documentation of such compliance upon request of PRHIA.

### **Section 3. Permitted Uses and Disclosures by Business Associate.**

3.1 Business Associate may use or disclose Protected Health Information, or any information derived from that Protected Health Information, only as explicitly permitted in the Underlying Agreements and this Agreement, and only if such use or Disclosure, respectively, is in compliance with each applicable requirement of 45 CFR § 164.504(e) and 164.314(a)(2). This means that:

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

3.1.2 Except as otherwise limited in this Agreement, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of Business Associate, provided that such disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person/organization 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/organization, and the person/organization notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been Breached.

3.1.3 In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any Subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information.

3.2 Business Associate understands and agrees that its access to Protected Health Information stored in databases and information systems at PRHIA is subject to review and audit by PRHIA, the Secretary, or agents of the HHS and OCR at any time, that remote audits of such access may occur at any time, that on-site audits of such access will be conducted during regular business hours, and that any review or audit may occur with or without prior notice by PRHIA. The fact that PRHIA reviews or audits, or fails to review or audit, or has the right to review and audit, Business Associate's access does not relieve Business Associate of the responsibility to comply with this Agreement, nor does PRHIA's (i) failure to detect or (ii) detection, but failure to notify Business Associate or to require Business Associate's remediation of any unsatisfactory practice, constitute acceptance of such practice or waiver of PRHIA's enforcement rights under this Agreement.

#### **Section 4. Application of Security and Privacy Provisions to Business Associate.**

4.1 Security Measures: The Security Rule, including 45 CFR §164.308, 164.310, 164.312 and 164.316, dealing with the administrative, physical and technical safeguards as well as policies, procedures and documentation requirements that apply to PRHIA shall in the same manner apply to Business Associate as Required By Law. If Business Associate requires access to PRHIA's electronic patient

information systems, electronic health record (EHR) or electronic infrastructure systems (either on site or remote), Business Associate will supply the necessary information of employees to uniquely identify such employees as employees with a need to access systems and will supply to PRHIA's Information Security Officer a valid state or federal issued photo ID in order for such employees to receive a unique user name and password to access the system(s).

4.2 Application of Civil and Criminal Penalties: If Business Associate violates any Security provision as Required By Law specified in Section 4.1 above, sections 1176 and 1177 of the Social Security Act, 42 U.S.C. §1320d-5, 1320d-6, shall apply to Business Associate with respect to such violation in the same manner that such sections apply to PRHIA if it violates such Security provision.

## **Section 5. Information Breach and Restriction Notification Requirements.**

5.1 Business Associate expressly recognizes that PRHIA may have certain reporting and Disclosure obligations to the Secretary and the Individual in case of a Security Breach of Unsecured Protected Health Information.

5.2 Where Business Associate uses or Discloses Unsecured Protected Health Information in a manner not permitted by this Agreement, Business Associate without unreasonable delay and in no case later than the timeframe set forth in Section 2.4 of this Agreement, following the discovery of any impermissible use, Disclosure, or Breach of such information, shall notify PRHIA of such Breach, use or Disclosure. Such notice shall include the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, accessed, acquired or disclosed. Business Associate shall cooperate with PRHIA to assist PRHIA in determining whether an impermissible use or Disclosure is a Breach, and shall provide a written risk assessment, in accordance with 45 C.F.R. §164.402, upon request of PRHIA.

5.3 Business Associate shall be liable for the costs associated with any Breach if caused by the Business Associate's negligent or willful acts or omissions, or the negligent or willful acts or omissions of Business Associate's agents, officers, employees or Subcontractors. PRHIA, in its sole and absolute discretion, may elect to delegate to Business Associate any requirement to notify affected Individuals of a Breach of Unsecured Protected Health Information, if such Breach results from,

or is related to, an act or omission of Business Associate or the subcontractors, agents, employees or representatives of Business Associate.

5.4 PRHIA agrees to notify Business Associate of any restrictions on the use or disclosure of Protected Health Information to which PRHIA has agreed that may affect Business Associate's use or disclosure of Protected Health Information pursuant to this Agreement.

## **Section 6. Insurance and Indemnification**

6.1 Indemnification. The Business Associate agrees to indemnify, defend and hold harmless PRHIA and PRHIA's employees, affiliates, directors, officers, Subcontractors, agents or other members of its workforce from any costs, damages, expenses, judgments, losses, and attorney's fees arising from any breach of this Agreement by Business Associate, or arising from any negligent or wrongful acts or omissions of Business Associate, including failure to perform its obligations under the Privacy Rule or Security Rule. The Business Associate's indemnification obligation shall survive the expiration or termination of this Agreement for any reason.

## **Section 7. Terms and Termination.**

7.1 Term. The Term of this Agreement shall commence as of the Effective Date (as defined below), and shall terminate on the latest termination date of the Underlying Agreements or on the date PRHIA terminates this agreement for cause as authorized on paragraph (7.2) of this section, whichever is sooner.

7.2 Termination for Cause. The Parties acknowledge that in the event the PRHIA learns of a pattern or activity or practice of the Business Associate that constitutes violation of a material term of this Agreement, then Business Associate promptly shall take reasonable steps to cure the violation. If such steps are, in the judgment of PRHIA, unsuccessful, ineffective or not feasible, then PRHIA may terminate, in its sole discretion, this Agreement and/or any or all of the Underlying Agreements upon written notice to the Business Associate, if feasible.

7.3 Effect of Termination. Except as provided in the following paragraph of this section, upon termination of this Agreement or the Underlying Agreements for any reason, Business Associate shall return or, only with PRHIA's prior written



permission, destroy all Protected Health Information received from PRHIA, or created or received by Business Associate on behalf of PRHIA. This provision shall apply to Protected Health Information that is in the possession of Subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information except as otherwise permitted by PRHIA.

In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to PRHIA notification, in writing, of the conditions that make return or destruction infeasible. Said notification shall include: (i) a statement that the Business Associate has determined that it is not feasible to return or destroy the Protected Health Information in its possession, and (ii) the specific reasons for such determination. PRHIA may disagree with the Business Associate's determination. Upon mutual agreement of the Parties that return or destruction of Protected Health Information is infeasible, Business Associate shall 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 as long as Business Associate maintains such Protected Health Information. If it is infeasible for the Business Associates to obtain, from a Subcontractor or agent, any Protected Health Information in the possession of the Subcontractor or agent, the Business Associate must provide a written explanation to PRHIA and require the Subcontractors and agents to agree to extend any and all protections, limitations, and restrictions contained in this Agreement to the Subcontractors' and/or agents' use and/or Disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses and/or Disclosures to the purposes that make the return or destruction of Protected Health Information infeasible.

7.4 Automatic Termination. This agreement will automatically terminate without any further action of the Parties upon the latest termination or expiration of the Underlying Agreements.

7.5 Effective Date. The effective date of this Agreement (the "Effective Date") shall be the date of the last signature below.

## **Section 8. Miscellaneous.**

8.1 Regulatory References. A reference in this Agreement to a section in the Privacy and Security Rules means the section as in effect or as amended, and for which compliance is required.

8.2 Agreement. The Parties agree to negotiate in good faith to take such action as is necessary to amend the Underlying Agreements from time to time as is necessary for PRHIA to comply with the requirements of HIPAA; provided, however, that the Agreement shall be modified only in accordance with Section 8.3 of this Agreement.

8.3 Amendments; Waiver. This agreement may not be modified, nor shall any provision hereof be waived or amended, except in a writing duly signed by authorized representatives of the Parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to a waiver of any right or remedy as to subsequent events. The Parties agree to negotiate in good faith 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 rules and any other applicable law.

8.4 Survival. Sections 2.3, 2.4, 2.6, 2.8, 2.10, 3.2, 5.2, 5.3, 6.1 and 7.3, 8.4, 8.5, 8.6, 8.7 and 8.8 shall survive the termination of this Agreement and/or the Underlying Agreements.

8.5 No Third Party Beneficiaries/Independent Contractors. Except as set forth in Section 6.1, 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 or assigns of the Parties, any rights, remedies, obligations, or liabilities whatsoever.

8.6 Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits PRHIA and Business Associate to comply with the HIPAA Privacy and Security Rules. In the event of a conflict between this Agreement and any Underlying Agreements, this Agreement shall control.

8.7 Notices. Any notice required or permitted by this Agreement to be given or delivered shall be delivered in accordance with the notice provisions of the

Underlying Agreements. The Parties may change their addresses for purposes of this Agreement by written notice to the other party.

8.8 Severability. Whenever possible, each provision of this Agreement shall be interpreted so as to be effective and valid under applicable law. If any provision of this Agreement should be prohibited or found invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity without invalidating the other of such provision or the remaining provisions of this Agreement.

8.9 Governing Law. To the extent not preempted by federal law, the Agreement shall be governed and construed in accordance with the laws governing the Underlying Agreements.

8.10 Assignment, Binding Nature, and Benefits. This Agreement binds and benefits the Parties, and their respective successors and permitted assigns. Business Associate may not assign or subcontract rights or obligations under this Agreement without the express written consent of PRHIA. PRHIA may assign its rights and obligations under this Agreement to any successor or affiliate.

8.11 Counterparts. This Agreement may be executed in multiple counterparts, which shall constitute a single Agreement, and by facsimile or pdf signatures, which shall be treated as originals.

IN WITNESS WHEREOF, the parties have duly executed this Agreement this \_\_\_\_\_, 2023.

\_\_\_\_\_  
[Company Name]  
[Signer Name]  
[Company Position]  
EIN: \_\_\_\_\_

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

\_\_\_\_\_  
Edna Y. Marín Ramos, MA  
Executive Director  
PR Health Insurance Administration  
EIN 66-0500678

Address:  
PO Box 195661  
San Juan, PR 00919-5661