

## HEALTH INFORMATION EXCHANGE (HIE) PARTICIPATION AGREEMENT

This Participation Agreement for HIE Access and Data Use (“Participation Agreement” or “Agreement”) is made and entered into by and between the Puerto Rico Department of Health (PRDoH) and \_\_\_\_\_ (“Participant”) by the Effective Date defined herein.

### WITNESSETH:

WHEREAS, the PRDoH seeks to facilitate the adoption of and promote the use of health information technology in the interests of quality of care, patient safety, and health care efficiency, while also maintaining patient data security and privacy.

WHEREAS, in support of these objectives, PRDoH through the Law 40 of 2012 created the Puerto Rico Health Information Exchange (PRHIE) who will operate and maintain the Health Information Exchange (HIE).

WHEREAS, as a condition of receiving Medicaid and Commonwealth funds, MCOs and Health Care Providers are required by law to connect to the HIE and submit, through the HIE, protected health information (“PHI”) and other confidential individual demographic and clinical information pertaining to health care services rendered to Medicaid, Puerto Rico Health Plan for Teachers and State Employees, and other Commonwealth-funded health care program beneficiaries and paid for with Commonwealth-funded health care funds;

WHEREAS, Participants may be required to submit or receive data through the HIE for other specified government purposes, such as for public health and registry reporting and investigation;

WHEREAS, a Participant may be both a Data Provider and a Data Recipient;

WHEREAS, other organizations that desire to electronically transact on their own behalf may voluntarily elect to become a Participant to submit or receive data through the HIE;

WHEREAS, as a condition of transacting information with other Participants, each Participant must enter into this Participation Agreement, and has agreed to do so by executing this Agreement;

NOW, THEREFORE, for and in consideration of the mutual covenants herein contained, the purpose of this Agreement is to provide a legal framework that will enable Participants to connect to the HIE to submit selected health Data to specified government programs as required or permitted by HITECH Act and other Applicable Law, to exchange health data with other Participants, and to access and use services provided by the HIE. The Participants enter into this Agreement to enable their participation in health information exchange activities, as set forth below.

### 1. DEFINITIONS

The following terms shall have the meaning ascribed to them in this section. Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in the federal Standards for Privacy of Individually Identifiable Health Information, HIPAA 45 CFR Parts 160, subpart A and 164, subparts A and E (the “Privacy Rule”); the federal Security Standards for the Protection of Electronic Protected Health Information, HIPAA 45 CFR Parts 160, subpart A and 164, subparts A and C (the “Security Rule”); and the Notification in the Case of Breach of Unsecured Protected Health Information, HIPAA 45 CFR Parts 164, subpart D (the “Breach Notification Rule”) (collectively, the “HIPAA Rules”).

**Authorized Use or Disclosure** means a use or disclosure of health information authorized by the individual to whom it pertains, or by that person's legal designee.

**Authorized User** means an individual authorized by HIE, a Data Provider or a Data Recipient under this Agreement to use the Exchange to access Data for a Permitted Use and who has signed an Authorized User Consent.

**Beneficiary** means a person who is a member of a health insurance plan, including Medicaid and Medicare. Individual may be used interchangeably with beneficiary.

**Breach** means a use or disclosure of PHI not permitted or authorized by law as defined by HIPAA 45 CFR Part 164.402.

**Business Associate** refers to a business or organization that performs certain administrative functions on behalf of an entity covered under HIPAA as defined by HIPAA 45 CFR Part 160.103.

**Data** means protected health information (PHI), or other Confidential information that identifies an individual, as provided to the HIE by Data Providers.

**Data Exchange** means electronically providing or accessing Data through the HIE.

**Data Recipient** means an individual or entity that has entered into an HIE Participation Agreement and whose Authorized Users will receive Data using the HIE. A Data Recipient may also be a Data Provider.

**Data Provider** means an individual or entity, such as a hospital, physician, clinical laboratory, pharmacy claims aggregation company, governmental agency or other entity that transmits and makes Data available for access through the HIE and has entered into a Participation Agreement. A Data Provider may also be a Data Recipient.

**Designated Record Set** includes all records maintained by or for a covered entity that are used to make treatment and payment decisions about an individual, such as:

- Medical records and billing records about individuals maintained by or for a covered healthcare provider;
- Enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or
- Other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals.

Designated record set is defined in HIPAA 45 CFR Part 164.501.

**Health Care Provider** means a physician, group practice, hospital or health system, or other health care organization or professional that provides treatment to Patients and has entered into an HIE Participation Agreement. A Health Care Provider may be a Data Provider, a Data Recipient, and an Authorized User. Health care provider is defined by HIPAA 45 CFR Part 160.103.

**Health Information Exchange** means an organization or process that enables the electronic exchange of health information between authorized entities.

**Individual** is the person the health information or PHI is about as defined in HIPAA 45 CFR Part 160.103. Patient may be used interchangeably with individual.

**Managed Care Organization** means an insurer that is contracted to provide Medicaid Managed Care in Puerto Rico. An MCO qualifies as a Health Plan and may be a Data Provider, a Data Recipient, and an Authorized User. Health plan is defined by HIPAA 45 CFR Part 160.103.

**Patient** means an individual who has received or will receive treatment or health care services from a Health Care Provider. Individual may be used interchangeably with patient.

**Participant** means a Data Recipient and/or Data Provider that has entered into a Participation Agreement, including the Participant named as a party to this Agreement.

**Permitted Use or Disclosure** defines purposes for which Participants and Authorized Users may access, use or disclose health information under certain legal conditions. Permitted uses and disclosures are defined by HIPAA 45 CFR Part 164.501, 164.506, and 164.512.

**Protected Health Information** is individually identifiable health information held by a covered entity or by a business associate on behalf of a covered entity as defined in HIPAA 45 CFR Part 160.103.

**Required by Law** means a use or disclosure of health information required by state or federal law as defined in HIPAA 45 CFR Part 164.103.

**Secretary** means the United States Secretary of the Department of Health and Human Services or his/her designee.

**Security Incident** means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of data/information or interference with system operations in an electronic information system. Security incident is defined in HIPAA 45 CFR Part 164.304.

**Unsecured Protected Health Information** Unsecured protected health information means PHI that is not rendered unusable, unreadable, or indecipherable through use of a method specified by the Secretary in the guidance issues under 13402(h)(2) of P.L. 111-5, as defined at HIPAA 45 CFR Part 164.402. Electronic PHI that is unencrypted or electronic/paper PHI that has not been physically destroyed (e.g., shredded) is considered unsecured.

## **2. DATA SHARING AND ACCESS**

**2.1. Limits on Uses and Disclosures.** Both parties will limit uses and disclosures of PHI and other Confidential Information (“Data”) to those required or permitted by law and as specified in this agreement. Neither party shall request or require any use or disclosure of Data that would not be permissible under the Privacy or Security Rules or any other applicable laws and regulations.

**2.2. Minimum Necessary.** All uses and disclosures of Data to any parties other than the patient to whom the information pertains will be limited to the minimum necessary for the purpose of the exchange.

**2.3. Data Exchange.** Individual PHI may only be shared with or through the HIE if the individual has been notified and given permission for their information to be exchanged electronically via a third party. Certain programs or organizations may require patient level data to be exchanged through the HIE, such as for Medicaid and certain public health reporting. In these cases, data sharing requirements will conform to those required for program participation as long as

patients/beneficiaries are notified and allowed to opt in/out of sending their PHI via electronic exchange, and if not in violation of other applicable laws.

**2.4. Data Access.** Both parties have rights to access the Data stored in the cloud-based clinical data repository per applicable laws and the terms of this agreement.

**2.5. Privacy and Security.** Both parties will comply with all applicable privacy and security requirements required by law and as specified in this agreement.

**2.5.1.Safeguards.** Both parties must utilize and maintain appropriate safeguards for the technology, exchanges, and information under their control.

**2.5.2.PHI and Other Confidential Information.** Both parties may use and disclose the Data of the other Party as necessary to perform their obligations under this Agreement and shall prevent inappropriate and unauthorized use, dissemination and disclosure of the other Party's Data.

**2.5.3.Privacy or Security Breach.** Both Parties shall promptly report any actual or potential breach of Data to the other party if that information has been exchanged via the HIE and/or exists in the cloud repository. All affected parties will cooperate to ensure that prompt mitigation measures are taken and timely breach notification is issued as outlined in state (10 L.P.R.A. § 4051) and federal law (45 CFR Part 164.410(c)).

**2.6. Participation Agreements.** All participants using the HIE's services will sign a Participation Agreement and abide by the terms therein.

**2.7. HIPAA Business Associate Agreement.** The Parties hereby agree to the terms and conditions of the HIPAA Business Associate Agreement. In the event of a conflict between the terms of this agreement and the terms of the Business Associate Agreement, the terms of the Business Associate Agreement shall govern to the extent of such conflict.

### **3. DATA RECIPIENT (HIE) OBLIGATIONS**

**3.1. HIE Services.** The HIE provides a secure platform to support electronic exchange of Data and business transactions in service of health care treatment, payment, and health care operations. Services available may be subject to change. Under this agreement, the HIE agrees to provide the following services:

- (1) Secure electronic exchange with government programs and other participants as defined in this agreement
- (2) Electronic patient record access via API
- (3) Electronic public health reporting
- (4) Cloud data repository
- (5) Patient portal for access of records

**3.2. HIE Operations.** The HIE shall conduct all exchange and operations openly and transparently. All terms, conditions, policies and contractual agreements that govern the exchange are publicly available.

**3.2.1. Security.** The HIE shall maintain the most current industry standards for data, system, and transmission security. The HIE uses cloud security to protect connectivity, exchanges, and data storage, and maintains compliance with HIPAA and Medicaid security requirements for data at rest and in transit.

**3.2.2. Cloud Storage/Data Warehouse.** Data exchanged through the HIE is stored in the cloud repository. The HIE supports a secure database using cloud security for storage and maintains compliance with HIPAA and Medicaid security requirements for data at rest.

**3.2.3. Patient/Provider Access.** Data in the cloud repository and residing across Data Providers participating in the HIE is available to patients and providers via HIE APIs.

**3.2.4. Technical Support.** The HIE will support operations 24/7. Technical support is available by contacting prhie@salud.gov.pr.

### **3.3. Data Governance**

**3.3.1. Uses and Disclosures.** All uses and disclosures of Data through and by the HIE are limited to those permitted by law and documented in this agreement. The HIE shall not engage in any uses or disclosures that are not expressly permitted or authorized as outlined in this agreement and under applicable law.

**3.3.2. Minimum Necessary.** All uses and disclosures of Data through and by the HIE must be limited to minimum necessary to accomplish the purpose of the request.

**3.3.3. Data Retention and Reuse.** All Data exchanged via the HIE will be maintained in a secure cloud-based clinical data repository to support analytics, patient record access, and other key capabilities requiring patient level data for all parties as authorized. Secondary uses and disclosures are limited to those required or permitted by law and as specified in this agreement when patient notification has been provided.

**3.3.4. De-identified Data Use.** De-identified data may be used regardless of opt-in/out for population reporting, business intelligence, mapping, program and service evaluation, analytic and statistical purposes, and other purposes that do not require use of or would indirectly reveal patient/beneficiary identifiers.

**3.3.5. Internal Data Use.** The HIE may use or disclose Data submitted as necessary for internal HIE management and administration or to carry out its legal responsibilities as permitted under the Privacy Rule, provided such uses and disclosures are required or permitted by federal law or the laws or regulations of the Commonwealth of Puerto Rico.

**3.3.6. Reporting.** The HIE may use Data as necessary to report violations of the law to the appropriate federal and state authorities, to the extent permitted by 45 CFR Part 164.502(j)(1).

**3.3.7. Data Aggregation.** The HIE may use Data to provide data aggregation services per 45 CFR Parts 164.504(e)(2)(i)(B).

**3.4. HIE Policies.** The HIE shall publish, keep current, and make publicly available the HIE's policies and privacy practices.

**3.5. Data Breaches and Investigations.** The HIE will immediately notify all affected Participants of any actual or potential breach of Data exchanged via the HIE and/or in the cloud repository. The HIE will cooperate with and assist as necessary the affected parties to ensure that breaches are thoroughly investigated, prompt mitigation measures are taken, and timely breach notification is issued.

**3.6. No Remuneration.** The HIE shall not directly or indirectly receive remuneration in exchange for any Data unless the data provider obtains written authorization from the individual who is the subject of the PHI that specifies that the PHI can be further exchanged for remuneration, except

for a cost-based fee to cover the cost to prepare and transmit the PHI for an authorized purpose, or a fee otherwise expressly permitted by other law when:

**3.6.1.**The purpose of the exchange is for research or public health activities as described in 45 CFR Part 164.512(i), 164.512(b) and 164.514(e), or

**3.6.2.**The purpose of the exchange is for the treatment of the individual, subject to 45 CFR Part 164.506(a), or

**3.6.3.**The purpose of the exchange is to provide an individual with a copy of the individual's PHI pursuant to 45 CFR Part 164.524 or an accounting of disclosures pursuant to 164.528.

**3.7. Fees and Other Costs.** No fee shall be levied on behalf of PRHIE for the exchange of data, using the preferred methods of connection.

**3.8. Business Associate Obligations.** The HIE as a business associate agrees to comply with the following provisions as required under 45 CFR Part 164.504:

**3.8.1.**Not use or disclose PHI other than as permitted under the Privacy Rule and as specified in this agreement;

**3.8.2.**To mitigate, to the extent practicable, any harmful effect of a use or disclosure of PHI in violation of the terms of this agreement;

**3.8.3.**To report to the Data Provider any impermissible use or disclosure of PHI of which it becomes aware;

**3.8.4.**If applicable, in accordance with 45 CFR Parts 164.504(e)(1)(ii) and 164.308(b)(2), to enter into written agreements with any subcontractors that create, receive, maintain or transmit PHI on behalf of the HIE, and the terms of such agreements shall incorporate the same restrictions, conditions, and requirements that apply to the HIE as a business associate;

**3.8.5.**At the sole cost and expense of the HIE, the HIE will provide access to PHI to Data Providers and patients/beneficiaries to meet the requirements under 45 CFR Part 164.524. These obligations apply only to PHI in the Designated Record Sets in the HIE's possession or control as defined in 45 CFR Part 164.501. Such access shall be provided in a reasonable and timely manner as agreed to by both parties and in compliance with required legal time frames.

**3.8.6.** At the sole cost and expense of the HIE, the HIE will make any amendment(s) to PHI that the Data Provider directs or agrees to pursuant to 45 CFR Part 164.526, in a time and manner reasonably agreed to by both parties and in compliance with required legal time frames. The HIE will direct any subcontractors who have access to that person's PHI to make those amendments as well. These obligations apply only to PHI in the Designated Record Sets in the HIE's possession or control as defined in 45 CFR Part 164.501.

**3.8.7.**At the sole cost and expense of the HIE, the HIE will abide by any restrictions to use and disclosure of PHI that the Data Provider directs or agrees to pursuant to 45 CFR Part 164.522, The HIE will direct any subcontractors who have access to that person's PHI to abide by those restrictions as well. These obligations apply only to PHI in the Designated Record Sets in the HIE's possession or control as defined in 45 CFR Part 164.501.

**3.8.8.**To make its internal practices, books and records, including any policies and procedures, available to the Secretary in a time and manner agreed upon or designated by the Secretary, for purposes of a federal audit or determining compliance with the Privacy and Security Rules.

**3.8.9.** To maintain and make available in a time and manner reasonably agreed to by both parties and in compliance with required legal time frames, any information required for the Data Provider to respond to a request by an individual for an accounting of disclosures, as necessary to comply with 45 CFR Part 164.528.

**3.8.10.** Agree to use appropriate safeguards and comply with applicable and mandatory requirements of the Security Rule as set forth in 45 CFR Parts 164.308, 164.312, and 164.316 with respect to electronic PHI to prevent the use or disclosure of electronic PHI other than as provided for by this agreement.

**3.8.11.** Shall report to the Data Provider any security incident that results in the unauthorized access, use or disclosure of electronic PHI from the data provider of which the HIE becomes aware with respect to electronic PHI the HIE creates, receives, maintains or transmits on behalf of the data provider. However, the following are examples of unsuccessful security incidents, if they do not result in a pattern of security incidents or the unauthorized access use, disclosure, modification or destruction of PHI or interference with the normal operations of an information system, do not need to be reported:

- (a) Pings on a firewall;
- (b) Port scans;
- (c) Attempts to log on to a system or enter a database with an invalid password or username;
- (d) Malware (e.g., worms, viruses)

**3.8.12.** Notify the Data Provider of any breaches of unsecured Data without unreasonable delay. Notice must include all applicable elements as set forth at 45 CFR Part 164.410(c) and in state law 10 L.P.R.A. § 4051. Individuals whose Data has been compromised must be notified as expeditiously as possible and within the legal time frame, taking into consideration the need of law enforcement agencies to secure possible crime scenes and evidence as well as the application of measures needed to restore the system's security. Within a non-extendable term of ten (10) days after the violation of the system's security has been detected, the Parties responsible shall inform the PR Department of Consumer Affairs, per 10 L.P.R.A. § 4051.

#### **4. DATA RECIPIENT (THIRD PARTY) RIGHTS AND OBLIGATIONS**

The rights and obligations of this Section apply to Data Recipients, organizations that receive or access Data through the HIE. This includes the HIE and providers who are not the original providers of the information. This does not include individual patients or beneficiaries. Data Recipient, its employees and agents will comply with this Agreement and all applicable laws and regulations governing the use, privacy, and security of Data made available via the HIE. If the Data Recipient is also a Data Provider, the provisions applicable to Data Providers will also apply.

**4.1. Data Exchange.** By exchanging Data via the HIE, Data Recipient agrees that its participation in electronic exchange and use of the HIE by Data Recipient and its Authorized Users will comply with the terms of this Agreement and applicable laws and regulations. Data Recipient also agrees that Data Recipient has secured any required Patient permission to access the Data via the HIE if needed for purposes other than treatment, payment, or health care operations, or for required or permitted purposes that do not require patient consent or authorization.

**4.2. Permitted Use.** Data Recipient and its Authorized Users will use the HIE only for a Permitted or Authorized Use. Data Recipient and its Authorized Users will comply with this Agreement and all applicable laws and regulations governing the use, privacy, and security of Data received through the HIE. Data Recipient will decide in its discretion whether to use the HIE, and to what extent.

**4.3. Minimum Necessary.** Data Recipients will limit any data requests of a Data Provider to the minimum necessary to accomplish the purpose of the request.

**4.4. Authorized Users.** Data Recipient will identify and authenticate its Authorized Users, in accord with the HIE's Policies and Standards, who may use the HIE for the Permitted Use on behalf of Data Recipient and will require each Authorized User to execute an Authorized User Consent to the Terms set forth in the BAA between the parties. Authorized Users will include only those individuals who require access to the HIE to facilitate Data Recipient's use of the Data for a Permitted Use. Participant is responsible for Authorized Users complying with the terms and conditions of this Agreement and applicable laws and regulations.

## **5. DATA PROVIDER RIGHTS AND OBLIGATIONS**

The rights and obligations of this Section apply to Data Providers, organizations that originate, receive or document Data directly from a patient/beneficiary encounter. This does not include the HIE, providers who are not the original providers of the information, or individual patients or beneficiaries. Data Provider, its employees and agents will comply with this Agreement and all applicable laws and regulations governing the use, privacy, and security of Data made available to the HIE. If the Data Provider is also a Data Recipient, the provisions applicable to Data Recipients will also apply.

**5.1. Data Exchange and Data Submission.** By engaging in electronic exchange, Data Provider agrees that: (a) its participation in the HIE will comply with the terms of this Agreement and applicable laws and regulations; (b) the Data provided or transferred by Data Provider can be related to and identified with source records maintained by Data Provider; and (c) Data Provider has secured all authorizations for the submission of Data. Data Provider will make Data available for the HIE in accordance with the scope, format, and specifications set forth in the BAA between the parties.

**5.2. Permitted Uses.** Data Provider and HIE acknowledge that Data Provider will make Data available for access through the HIE only for a Permitted or Authorized Use. The parties acknowledge that certain uses of Data, including without limitation Treatment, Payment and certain Health Care Operations (as defined by 45 C.F.R. Part 164, Subpart E) do not require specific consent by a Patient under HIPAA or Puerto Rico Law.

**5.3. Patient Notice of HIE Participation/Opt-in/Out.** Any individual whose health information may be shared with or through the HIE, regardless of the purpose, must be notified that their information will be exchanged electronically via a third party. The Data Provider is responsible for securing consent to supply Patient's Data to the HIE. All persons have the right to refuse to have their information shared via the HIE. Health care providers and health plans must give their patients/beneficiaries the opportunity to opt out from having their information sent via the HIE. That choice will be retained in the patient's/beneficiary's files and can be changed at any time. Data Providers will also notify the HIE whenever a patient revokes permission to send their information through the HIE. The opt out form is available through the HIE website at [http://www.salud.gov.pr/Dept-de-Salud/PublishingImages/Pages/Puerto-Rico-Health-Information-Exchange-\(PRHIE\)-Participantes/Formulario%20de%20Consentimiento%20de%20Exclusion%20Voluntaria.pdf](http://www.salud.gov.pr/Dept-de-Salud/PublishingImages/Pages/Puerto-Rico-Health-Information-Exchange-(PRHIE)-Participantes/Formulario%20de%20Consentimiento%20de%20Exclusion%20Voluntaria.pdf)

**5.4. Notification of Notice of Privacy Practices.** Data Providers operating in a health care provider or health plan role must notify the Data Recipient of any limiting provisions in their Notice of Privacy Practices that may impact any patient data previously exchanged and stored in the cloud repository and provide a copy of that Notice.



**5.5. Notification of Patient Amendments, Restrictions and Authorizations.** Data Providers operating in a health care provider or health plan role must notify the Data Recipient of any patient amendments or restrictions that may impact any patient data previously exchanged and stored in the cloud repository. Data Providers will also notify the HIE whenever a patient revokes an authorization and/or when an authorization expires, if applicable.

**5.6. Complaints.** Data Providers that have concerns about how the HIE is handling, protecting, or sharing the Data exchanged through the HIE should contact the Designated State HIT Coordinator to report any issues. Data Providers can also submit a complaint to the Office for Civil Rights (OCR) in the Department of Health and Human Services (DHHS).

## **6. Term and Termination**

**6.1. Term.** This Agreement shall continue in effect until terminated hereunder, commencing on the Effective Date unless terminated as set forth herein. The obligations under this Agreement shall apply to each transaction made under and/or referencing this Agreement until the later of (i) completion, termination, or expiration of this Agreement or (ii) when all of the PHI provided by the **Covered Entity** to the **HIE** or created received, maintained, or transmitted by the **HIE** on behalf of the Covered Entity under this Agreement is destroyed or returned to the **Covered Entity**, in accordance with subsection 6.3, below.

**6.2. Termination.** Either Party may terminate this Agreement without cause or penalty at any time by providing ninety (90) days' written notice to the other Party. Termination may be for:

**6.2.1. Material Breach.** This Agreement may be immediately terminated by either party upon fifteen (15) days' prior written notice to the other Party of a Default Event (as defined below); provided that such Default Event (if capable of cure during such period) has not been cured.

**6.2.2. Third Party Technology Providers.** PRDoH may terminate this Agreement immediately in the event the vendor agreement by and between PRDoH for the technology used to run the HIE terminates for any reason.

**6.2.3. Privacy and Security Non-Compliance.** Either party may terminate this Agreement immediately if the entity is found to be in non-compliance with federal and Commonwealth privacy and security regulations, or any other regulations which impose significant risk to one or both parties, unless doing so would violate terms of participation in another government program.

**6.2.4. Regulatory Non-Compliance.** Either party may terminate this Agreement immediately if the entity is found to be in non-compliance with other federal and Commonwealth regulations which impose significant risk to one or both parties.

### **6.3. Effect of Termination**

**6.3.1.** Except as provided below in paragraph 6.3.2 of this subsection, upon termination of this Agreement, for any reason, the PRDoH shall return or destroy all PHI received from Participant or created, received, maintained, or transmitted by the PRDoH on behalf of the Participant in accordance with HIPAA. This provision shall apply to PHI in the possession of subcontractors or agents of PRDoH. PRDoH shall retain no copies of PHI received from Participant.

**6.3.2.** In the event PRDoH determines returning or destroying the PHI is unfeasible, PRDoH shall provide to Participant notification of the conditions that make return or destruction unfeasible,

PRDoH shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of PHI for so long as PRDoH maintains such PHI.

**6.4. Indemnification:** To the extent authorized under the Constitution and Laws of the Commonwealth of Puerto Rico, the Parties agree to hold each other harmless for any omission or negligent act caused by any person involved in the obligations and/or activities established under this Agreement.

Pursuant to Act Number 98 of August 24, 1994, which amends article 41.050 of the Puerto Rico Insurance Code, the Participant is limited to the sum of Seventy Five Thousand Dollars (\$75,000.00) for damages suffered by a person or his/her property, and up to One Hundred and Fifty Thousand Dollars (\$150,000.00) when the damages are caused to more than one person or when there are several causes of action to which one single injured party is entitled.

In the event that any claim, demand, action or suit occurs because of any action or inaction released to this Agreement, then the Parties involved agree to cooperate and reasonably assist each other in the investigation, evaluation, resolution, and/or defense of same by their respective attorneys, employees, agents or representatives.

## **7. Miscellaneous**

**7.1.1. Amendment** No amendment to this Agreement will be binding to the parties unless such amendment is reduced to writing and signed by both parties.

**7.1.2. Regulatory References** A reference in this Agreement to a section in HIPAA, HITECH or the HIPAA Regulations means the section as in effect or as amended, and for which compliance is required.

**7.1.3. Survival** The respective rights and obligations of PRDoH under section 6 (Term and Termination) of this Agreement shall survive termination of this Agreement.

**7.1.4. Interpretation** Any ambiguity in this Agreement shall be resolved to the extent reasonable to permit Participant to comply with HIPAA.

**7.1.5. Entire Agreement** This Agreement constitutes the entire understanding between the Parties with respect to the subject matter contained therein. No oral representations of any officer, agent, or employee of the Parties shall effect or modify any obligations under this Agreement.

**7.1.6. Non-Assignment** PRDoH may not assign this Agreement without the prior written consent of the Participant.

**7.1.7. Governing Law** This Agreement will always be subject to the laws and regulations of the Commonwealth of Puerto Rico and will be interpreted accordingly. If any of the clauses, paragraphs, sentences, words or parts of this Agreement shall continue in effect to ensure the intent of the Parties, which may be interpreted in accordance with the applicable provisions of the Civil Code of Puerto Rico and the laws governing the contracting parties with the Commonwealth of Puerto Rico.

**7.1.8. Captions** The captions are solely for the convenience of the Parties and shall not be used in the construction of this Agreement.

**7.1.9. Notice** All notices required to be given to either party under this Agreement will be in writing and sent by traceable carrier to each party's address, or such other address as a party may indicate by at least ten (10) days prior written notice to the other party. Notices will be effective upon receipt.

**IN WITNESS THEREOF**, the Parties hereto signs this Agreement, in San Juan, Puerto Rico, today \_\_\_\_\_, **2022**

**PUERTO RICO DEPARTMENT OF HEALTH**

**CARLOS R. MELLADO LOPEZ, MD**  
**SECRETARY OF HEALTH**

**PARTICIPANT**

**NAME**

**COMPANY**

**CERTIFICATION**

I, \_\_\_\_\_ Attorney for the legal Division of the Puerto Rico Department of Health, hereby certify that I have reviewed this agreement, and that it complies with the required format and mandatory clauses.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_