

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (this “**Agreement**”) is entered into this ____ day of _____, 20____ (the “**Effective Date**”), by and between the Delaware Health Information Network, a not-for-profit public instrumentality of the State of Delaware with a principal place of business at 107 Wolf Creek Blvd., Suite 2, Dover, DE 19901 (“**Business Associate**”), and **PRACTICE NAME** (“**Covered Entity**”). Business Associate and Covered Entity hereafter may be referred to individually as a “**Party**” and collectively, as the “**Parties.**”

RECITALS

WHEREAS, the Parties have entered, and may in the future enter, into one or more services agreement(s) (each a “**Services Agreement**”) that require Business Associate to perform functions or activities on behalf of, or services for, Covered Entity or an affiliate of Covered Entity that involve the use or disclosure of PHI (as hereafter defined) pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended (“**HIPAA**”), the Health Information Technology for Economic & Clinical Health Act and the Omnibus Final Rule (78 FR 5566) (the “**HITECH Act**”), as either HIPAA and the HITECH Act have been or may be amended, and the privacy and security and breach notification regulations published by the U.S. Department of Health and Human Services (“DHHS”) contained at 45 C.F.R. Parts 160 and 164, which may be periodically revised or amended (collectively, the “**HIPAA Regulations**”);

WHEREAS, it is the intent of Covered Entity and Business Associate to protect the privacy and provide for the security of PHI disclosed to the Business Associate in compliance with HIPAA and the HITECH Act and the HIPAA Regulations; and

WHEREAS, the Service Agreements include the legal and regulatory framework through which Covered Entity provides Data (as defined in the Service Agreement(s)) to Business Associate and accesses Data in Business Associate’s possession, as well as all of the agreements referred to in Business Associate’s Practice Toolkit;

WHEREAS, Business Associate provides health information exchange services Covered Entity pursuant to the Services Agreement(s); and

WHEREAS, the HIPAA Regulations require that Covered Entity and Business Associate enter into a written contract or other arrangement that meets the applicable requirements of 45 C.F.R. §§ 164.314 and 164.504;

WHEREAS, the Parties contemplate that Business Associate may obtain PHI, with Covered Entity’s knowledge, from certain other business associates of Covered Entity that may possess such PHI; and

WHEREAS, the Parties are entering into this Agreement to set forth Business Associate’s obligations with respect to its handling of the PHI, whether such PHI was obtained from another business associate of Covered Entity or directly from Covered Entity.

NOW, THEREFORE, for mutual consideration, the sufficiency and delivery of which is acknowledged by the Parties, and upon the premises and covenants set forth herein, the Parties intending to be legally bound hereby agree as follows:

1. Recitals; Definitions.

(a) The provisions of the Recitals set forth above are incorporated herein by reference.

(b) Unless otherwise defined herein, capitalized terms used in this Agreement shall have the meanings set forth in the HIPAA Regulations.

(i) “**Breach**” shall have the same meaning as the term “breach” in 45 C.F.R. §164.402.

(ii) “**Business Associate**” shall have the same meaning as the term “business associate” in 45 C.F.R. § 160.103.

(iii) “**Covered Entity**” shall have the same meaning as the term “covered entity” in 45 C.F.R. § 160.103.

(iv) “**Designated Record Set**” shall have the same meaning as the term “designated record set” in 45 C.F.R. §164.501.

(v) “**Electronic PHI**” shall have the same meaning as the term “electronic protected health information” in 45 C.F.R. §160.103, limited to the PHI created, received, maintained or transmitted by or on behalf of Covered Entity to Business Associate as contemplated by this Agreement.

(vi) “**HIPAA Breach Notification Rule**” shall mean the federal breach notification regulations, as amended from time to time, issued under HIPAA and set forth in 45 C.F.R. Part 164 (Subpart D).

(vii) “**Individual**” shall have the same meaning as the term “individual” in 45 C.F.R. §160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. §164.502(g).

(viii) “**PHI**” shall have the same meaning as the term “protected health information” in 45 C.F.R. §160.103, limited to the PHI created, received, maintained, or transmitted by or on behalf of Covered Entity to Business Associate as contemplated by this Agreement.

(ix) “**Privacy Rule**” shall mean the federal privacy regulations, as amended from time to time, issued under the HIPAA and the HITECH Act and set forth in 45 C.F.R. Parts 160 and 164 (Subparts A & E).

(x) “**Security Rule**” shall mean the federal security regulations, as amended from time to time, issued under the HIPAA and the HITECH Act and set forth in 45 C.F.R. Parts 160 and 164 (Subparts A & C).

(xi) “**Subcontractor**” shall have the same meaning as the term “subcontractor” in 45 C.F.R. §160.103.

2. Obligations and Activities of Business Associate. To the extent that Business Associate is provided with or creates any PHI on behalf of Covered Entity and is acting as a business associate of Covered Entity, Business Associate agrees to comply with the provisions of HIPAA applicable to business associates, and in doing so, represents and warrants as follows:

(a) **Use or Disclosure.** Business Associate agrees to not use or disclose PHI other than as set forth in this Agreement, the Services Agreement, or as Required by Law.

(b) **Specific Use of Disclosure.** Except as otherwise limited by this Agreement, Business Associate may:

(i) use or disclose PHI to perform data aggregation and other services required under the Services Agreement(s) to assist Covered Entity in its operations, as long as such use or disclosure would not violate HIPAA if done by Covered Entity, or HIPAA permits such use or disclosure by a business associate; and

(ii) use or disclose PHI for the proper management and administration of Business Associate or to carry out Business Associate’s legal responsibilities, provided that with respect to disclosure of PHI, such disclosure is Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially 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 Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached; and

(iii) use or disclose PHI for other lawful purposes as permitted under HIPAA.

(c) **Minimum Necessary.** Business Associate agrees to take reasonable efforts to limit requests for, or uses and disclosures of, PHI to the extent practical, a limited data set, otherwise to the minimum necessary to accomplish the intended request, use, or disclosure.

(d) **Safeguards.** Business Associate shall establish and use appropriate administrative, physical and technical safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to Electronic PHI, to prevent any use or disclosure of PHI not expressly authorized by this Agreement.

(i) To the extent that Business Associate creates, receives, maintains, or transmits Electronic PHI, Business Associate agrees to establish administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the Electronic PHI that it creates, receives,

maintains, or transmits on behalf of Covered Entity, as required by the Privacy Rule and the Security Rule.

(ii) The safeguards established by Business Associate shall include securing PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity in accordance with the standards set forth in HITECH Act §13402(h) and any guidance issued thereunder.

(iii) Business Associate agrees to provide Covered Entity with such written documentation concerning safeguards as Covered Entity may reasonably request from time to time.

(e) **Subcontractors.** Business Associate agrees to obtain written assurances that any Subcontractors to whom it provides PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, agree to the same restrictions and conditions that apply to Business Associate with respect to such PHI, including the requirement that it agree to implement reasonable and appropriate safeguards to protect Electronic PHI that is disclosed to it by Business Associate.

(f) **Reporting.** Within five (5) business days after discovery by Business Associate, or by Covered Entity, as the case may be, Business Associate or Covered Entity, as applicable, agrees to notify the other party in writing of any incident that involves an unauthorized acquisition, access, use, or disclosure of PHI, including any Breach of unsecured PHI, not provided for by this Agreement or the Services Agreement(s), of which Business Associate may become aware.

(i) In the notice provided to Covered Entity or Business Associate by Business Associate or Covered Entity, as the case may be, regarding unauthorized uses and/or disclosures of PHI, Business Associate shall describe the remedial or proposed mitigation efforts required under Section 2(g) of this Agreement.

(ii) Specifically with respect to reporting a Breach of Unsecured PHI, Business Associate or Covered Entity, as the case may be, agrees to include the identity of the Individual(s) whose unsecured PHI was Breached in the written notice provided to Covered Entity or Business Associate, and any additional information required by HIPAA.

(iii) Business Associate and Covered Entity agree to cooperate upon report of any such Breach so that the affected party may provide the Individual(s) affected by such Breach with proper notice as required by HIPAA.

(g) **Mitigation.** Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate resulting from a use or disclosure of PHI by Business Associate in violation of the requirements of this Agreement or the Services Agreement(s).

(h) **Audits and Inspections.** Business Associate agrees to make its internal practices, books, and records, including policies and procedures, relating to the use and disclosure of PHI available to the Secretary, in a time and manner mutually agreed to by the Parties or

designated by the Secretary, for purposes of the Secretary determining the Covered Entity's compliance with HIPAA, the HITECH Act, and the HIPAA Regulations.

(i) **Accounting.** Business Associate shall (i) make available to Covered Entity information to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI, or, if requested by Covered Entity, to make that information available directly to an Individual, all in accordance with 45 C.F.R. § 164.528 and any subsequent regulations issued thereunder; (ii) notify Covered Entity in writing after Business Associate's receipt directly from an Individual of any request for access to or amendment of PHI, or an accounting of disclosures, as contemplated by this Agreement; and (iii) maintain electronic records of all such disclosures for a minimum of six (6) calendar years. Nothing in this paragraph shall prevent Business Associate from directly providing an Individual with an accounting of disclosures of PHI made by Business Associate as described in the Privacy Rule.

(j) **Designated Record Set.** While the Parties do not intend for Business Associate to maintain any PHI in a Designated Record Set, to the extent that Business Associate does maintain any PHI in a Designated Record Set, Business Associate agrees to make available to Covered Entity PHI within fourteen (14) days:

(i) for Covered Entity to comply with its access obligations in accordance with 45 C.F.R. §164.524 and any subsequent regulations issued thereunder; and

(ii) for amendment upon Covered Entity's request and incorporate any amendments to PHI as may be required for Covered Entity comply with its amendment obligations in accordance with 45 C.F.R. §164.526 and any subsequent guidance.

(k) **HITECH Compliance Dates.** Business Associate agrees to comply with the HITECH Act provisions expressly addressed, or incorporated by reference, in this Agreement as of the effective dates of applicability and enforcement established by the HITECH Act and any subsequent regulations issued thereunder.

3. Obligations of Covered Entity.

(a) Covered Entity agrees to notify Business Associate of any:

(i) limitation(s) in Covered Entity's notice of privacy practices in accordance with 45 C.F.R. §164.520, to the extent that such limitation may affect Business Associate's use or disclosure of PHI;

(ii) changes in, or revocation of, permission by Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI; and

(iii) restriction to the use or disclosure of PHI 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 PHI.

(b) Covered Entity agrees to limit its use, disclosure, and requests of PHI pursuant to this Agreement to a limited data set or, if needed by Covered Entity, to the minimum necessary PHI to accomplish the intended purpose of such use, disclosure, or request.

4. Term and Termination.

(a) **Term.** This Agreement shall (i) commence on the Effective Date and, unless otherwise terminated as provided herein, (ii) have a term that shall run concurrently with that of the later of the expiration date or termination of the Services Agreement(s).

(b) **Termination Upon Breach.**

(i) Without limiting the termination rights of the Parties pursuant to the Services Agreement(s), upon either Party's knowledge of a material breach by the other Party to this Agreement, the non-breaching Party shall provide written notice of the breach or violation to the breaching Party that specifies the nature of the breach or violation and the breaching Party shall have thirty (30) days from the date of notification to the non-breaching Party to cure such breach. In the event that such breach is not timely cured to the reasonable satisfaction of the non-breaching Party, or timely cure is infeasible, the non-breaching Party shall have the right to immediately terminate this Agreement and those portions of the Services Agreement(s) that involve the disclosure to Business Associate of PHI, or, if nonseverable, the Service Agreement(s). Business Associate shall also have the right to terminate this Agreement in the event that the Covered Entity fails to comply with HIPAA in any way not otherwise specified herein.

(c) **Effect of Termination.**

(i) Upon termination of this Agreement for any reason, Business Associate, with respect to PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

(A) Retain only that PHI that is necessary for Business Associate to continue its proper management and administration;

(B) Return or destroy, if feasible, all remaining PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that Business Associate maintains in any form;

(C) Continue to use appropriate safeguards and comply with Subpart C of 45 C.F.R. Part 164 with respect to Electronic PHI to prevent use or disclosure of the PHI, other than as provided for in this Section, for as long as Business Associate retains the PHI;

(D) Not use or disclose the PHI retained by Business Associate other than for the purposes for which such PHI was retained and subject to the same conditions set out above that applied prior to termination; and

(E) Return or destroy, if feasible, all PHI retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration.

(ii) The obligations of Business Associate pursuant to this Section shall survive the termination of this Agreement and shall continue to bind Business Associate, its employees, Subcontractors, successors, and assigns as set forth herein.

5. Miscellaneous.

(a) **Regulatory References.** Any references in this Agreement to a section in HIPAA, the HITECH Act, or the HIPAA Regulations means the section as in effect or as amended.

(b) **Amendment; Compliance.** This Agreement may be amended or modified only in a writing signed by the Parties; provided, however, that the Parties acknowledge that the provisions of this Agreement are designed to comply with HIPAA, the HITECH Act, and the HIPAA Regulations and agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of HIPAA. Regardless of the execution of a formal amendment of this Agreement, this Agreement shall be deemed amended to permit the Covered Entity and Business Associate to comply with HIPAA, the HITECH Act, and the HIPAA Regulations.

(c) **Method of Providing Notice.** All notices will be written and sent by certified mail or commercial courier, postage prepaid, return receipt requested and/or by electronic mail (providing proof of delivery), addressed as set forth below. Any written notice will be deemed received on the date indicated on the return receipt or electronic proof of delivery, as applicable, or three (3) business days after the date on which the notice was sent, whichever is earlier. Either Party may alter the address to which notices are to be sent by giving notice of such change of address in conformity with the provisions of this Section for the giving of notice.

Notice to Covered Entity:

[insert address, including e-mail address if requested]

Notice to Business Associate:

107 Wolf Creek Blvd.
Dover, DE 19901
Attn: BAA Notice; General Counsel
Email for copy: Scott.Perkins@dhin.org; jan.lee@dhin.org

(d) **Parties Bound.** This Agreement shall inure to the benefit of and be binding upon the Parties hereto and their respective legal representatives, successors, and assigns. Neither Party may assign its respective rights and obligations under this Agreement without the prior written consent of the non-assigning Party; *provided, however, that* either Party may assign its rights and obligations under this Agreement to any successor or affiliated entity.

(e) **No Waiver.** No provision of this Agreement or any breach thereof shall be deemed waived unless such waiver is in writing and signed by the Party claimed to have waived such provision or breach. No waiver of a breach shall constitute a waiver of or excuse any different or subsequent breach.

(f) **Entire Agreement; Control of More Restrictive Provisions; Amendment; Effect on Agreement.** This Agreement, together with the Services Agreement(s), constitutes the complete agreement between the Parties and supersedes all prior and contemporaneous representations or agreements, whether oral or written, with respect to such matters. In the event of any conflict between the provisions of this Agreement and the provisions of the Services Agreement(s), the provisions of this Agreement shall control unless the provisions of such Services Agreement(s) are stricter, as reasonably determined by Covered Entity, with respect to PHI and still complies with HIPAA, or the Parties specifically otherwise agree in writing. No oral modification or waiver of any of the provisions of this Agreement shall be binding on either Party. No obligation on either party to enter into any transaction is to be implied from the execution or delivery of this Agreement.

(g) **Interpretation.** Any ambiguity in this Agreement shall be resolved to permit compliance with HIPAA, the HITECH Act, or the HIPAA Regulations.

(h) **No Third Party Rights.** Except as stated herein, the terms of this Agreement are not intended nor should they be construed to grant any rights, remedies, obligations, or liabilities whatsoever to parties other than the Parties and their respective successors or assigns.

(i) **Applicable Law.** This Agreement shall be governed under the laws of the State of Delaware, without regard to choice of law principles.

(j) **Judicial and Administrative Proceedings.** In the event that Business Associate receives a subpoena, court or administrative order, or other discovery request or mandate for release of PHI, Business Associate agrees to collaborate with Covered Entity with respect to Business Associate's response to such request. Business Associate shall notify Covered Entity within seven (7) days of receipt of such request or mandate.

(k) **Transmitting Electronic PHI.** Electronic PHI transmitted or otherwise transferred from or between Covered Entity and Business Associate must be encrypted by a process that renders the Electronic PHI unusable, unreadable, or indecipherable to unauthorized Individuals within the meaning of HITECH Act § 13402 and any implementing guidance including, but not limited to, 42 C.F.R. § 164.402.

(l) **Counterparts and Electronic Signature.**

(i) The Parties may sign this Agreement in one (1) or more counterparts by the duly authorized representatives of the Parties, each of which constitutes an original and all of which taken together shall constitute the Agreement; provided, however, that this Agreement shall not be in force and effect until the counterparts are exchanged.

(ii) The Parties may sign and deliver this Agreement by emailed portable document format ("PDF") document (or other mutually agreeable document

format), and a reproduction of this Agreement with a Party's signature made by PDF, sent by email, shall have the same effect as and be enforceable as a signed and delivered original version of this Agreement. The Parties hereby agree that any electronic signatures hereto are legal, valid, and enforceable as originals

(m) **Time**. Time is of the essence for all dates and time periods in this Agreement.

(n) **Severability**. The provisions of this Agreement are independent of and separable from each other, and no provision will be affected or rendered invalid or unenforceable by virtue of the fact that for any reason any other or others of them may be invalid or unenforceable in whole or in part.

(o) **Further Assurances**. Each Party agrees that to timely take all such actions as may be necessary from time to time to effectuate the provisions of this Agreement.

(p) **Relationship between the Parties**. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effectuating the provisions of this Agreement.

(q) **Jurisdiction and Venue**. For any dispute or action between the Parties, each of the Parties irrevocably and unconditionally:

(i) Submits to the exclusive jurisdiction and venue of the state courts sitting in the State of Delaware;

(ii) WAIVES ANY RIGHT TO A TRIAL BY JURY OR TO A CHANGE IN VENUE OR JURISDICTION FOR ANY DISPUTE; and

(iii) Agrees that service of process may be made by the manner set forth herein for the giving of notices.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement to be effective on the date set forth above.

COVERED ENTITY

(Signature)

(Name)

(Title)

(Date)

BUSINESS ASSOCIATE
Delaware Health Information Network

(Signature)

(Name)

(Title)

(Date)

[Signature Page to Business Associate Agreement]