

MEMORANDUM OF AGREEMENT

Parties

This Memorandum of Agreement (MOA) is made between the County of Santa Barbara, a political subdivision of the State of California (County) by and through its County Health Department, Public Health Laboratory (PHL) and Primary Diagnostics, Inc. (Primary). The parties to this agreement may be referred to herein collectively as the “Parties” or individually as a “Party”.

Recitals

WHEREAS, Primary provides public health laboratory computer connectivity services between the State and California County public health laboratories to optimize Santa Barbara Public Health laboratory’s capacity for current testing of future COVID-19 or other infectious disease services.

WHEREAS, Primary provides a seamless connection among the State’s public health labs for COVID-19 or other infectious disease services on Primary’s platform (Primary Connect) to allow data exchange.

WHEREAS, the Parties receive funds for participating in the Primary Integration Project from the California Department of Public Health (CDPH), which creates a mechanism to distribute testing between the public health labs based on real-time available capacity.

WHEREAS, CDPH is paying for the connectivity between Primary and the PHL Laboratory Information Management System (LIMS) Orchard and will maintain the cost of the interconnect in the future.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants and promises set forth below, the Parties hereto agree as follows:

1. Administration of Agreement:

Each Party identifies the following individual to serve as the authorized administrative representative for that Party. Any Party may change its representatives at any time by notifying the other Party in writing of such change and listing its effective date.

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| <p><u>Santa Barbara Public Health Laboratory (PHL)</u></p> <p>Henning Ansorg, MD FACP Public Health Officer County of Santa Barbara Health Department 300 N San Antonio Rd, Santa Barbara, CA 93110 Phone: (805) 681 5152, FAX (805) 681 4069 HAnsorg@sbcphd.org</p> | <p><u>Primary Diagnostics, Inc.</u></p> <p>Andrew Kobylinski CEO 595 Pacific Avenue Floor 4, San Francisco, CA 94133 (415) 216-3295 andrew@primary.health</p> |
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| <p>Thomas Rush DrPH, MPH, PHM Laboratory Director County of Santa Barbara Public Health Laboratory 300 N San Antonio Rd, Santa Barbara, CA 93110 (805) 681-2555 Office (805) Fax 805-681-5347 TRush@sbcphd.org</p> | |
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2. Notices:

Any notice or consent required or permitted to be given under this Agreement shall be given to the respective parties in writing, by personal delivery or facsimile, or with postage prepaid by first class mail, registered or certified mail, or express courier service, as follows:

To COUNTY: 300 N San Antonio Rd, Santa Barbara, CA 93110

To PRIMARY: 595 Pacific Avenue Floor 4, San Francisco, CA 94133

or at such other address or to such other person that the parties may from time to time designate in accordance with this Notices section. If sent by first class mail, notices and consents under this section shall be deemed to be received five (5) days following their deposit in the U.S. mail. This Notices section shall not be construed as meaning that either party agrees to service of process except as required by applicable law.

3. County Responsibilities:

- 3.1. Participate in the integration kick off meeting, touch point meetings, and attend the exercise trial or additional trials as required after integration is complete.
- 3.2. County IT's vendor OrchardSoft will assist in the integration project and maintain the PHL's LIMS Application Programming Interface, for the purpose of allowing different Public Health Laboratory Information Systems (LIMs) to be connected to each other.

4. Primary Responsibilities:

- 4.1. Complete the following phases according to Primary's CDPH work order Agreement Number 20-10982 including any and all amendments made to Agreement Number 20-10982 as it relates to Santa Barbara Public Health Laboratory IT integration. Primary shall:
 - 4.1.1. Phase 1 – Integration with each LIMS: Integrate Primary Connect with the County's PHL's LIMS system to allow for seamless connection among the State public health labs.
 - 4.1.2. Phase 2 – Labs of the Same LIMS Transfers Orders: Reroute orders from the other California County's PHL's that were transmitted via the LIMS system to the Santa Barbara County Public Health Lab so the test results can accurately be sent and

received. Primary will also enable cross-laboratory sample routing and backup testing among the same LIMS.

- 4.1.3. Phase 3 – Labs of Different LIMS Transfer Orders: Enable labs of different LIMS to transfer orders and facilitate a bidirectional and accurate rerouting of specimens. Primary will successfully reroute the orders from the County's PHL and/or LIMS to labs under different LIMS systems.

- 4.1.3.1 Provide ongoing maintenance and support to onboard Santa Barbara County's PHL onto the Primary Connect platform including trainings, support ongoing updates and requests to support end-user experience, data hosting, related infrastructure, and Application Programming Interface API endpoint maintenance.

- 4.2 Designate a Privacy Official and a Security Official to oversee its privacy and security requirements herein.
- 4.3 Sign County's Business Associate Agreement (Exhibit A). n

5. Indemnity:

County shall not be liable for, and Primary shall defend and indemnify County and the employees and agents of County (collectively "County Parties"), against any and all claims, demands, liability, judgments, awards, fines, mechanics' liens or other liens, labor disputes, losses, damages, expenses, charges or costs of any kind or character, including attorneys' fees and court costs (hereinafter collectively referred to as "Claims"), related to this Agreement or the work covered by this Agreement and arising either directly or indirectly from any act, error, omission or negligence of Primary or its contractors, licensees, agents, servants or employees, including, without limitation, Claims caused by the sole passive negligent act or the concurrent negligent act, error or omission, whether active or passive, of County Parties. Primary shall have no obligation, however, to defend or indemnify County Parties from a Claim if it is determined by a court of competent jurisdiction that such Claim was caused by the sole negligence or willful misconduct of County Parties. Primary shall defend County with competent counsel and County shall have the right to approve counsel. Such approval shall not be unreasonable withheld. Primary shall not settle claims against the County without the County's express written consent and such consent shall not be unreasonable withheld

6. Insurance:

Each Party must obtain at its own cost and expense and keep in full force and effect during the term of this MOA, including all extensions, policies of insurance or programs of self-insurance with policy limits of at least \$2,000,000 per occurrence or claim to cover any and all potential liability of such party hereunder. Minimum policy limits maintained by any Party shall in no way limit the Party's indemnification obligations. Primary shall name County as an additional insured under all applicable policies obtained by Primary related to the conduct of this Agreement.

7. Conformance with Law:

County of Santa Barbara Public Health Department and Primary Diagnostics MOA
2025-2030

All Parties shall be in conformity with all applicable provisions of (a) constitutions, treaties, statues, laws (including the common law), rules, regulations, decrees, ordinances, codes, policies, guidance, or orders of any Governmental Authority; (b) any consents or approvals of any Governmental Authority; and (c) any orders, decisions, injunctions, judgments, awards, decrees of, or agreements with, any Governmental Authority, in each case to the extent such items have the force of law as applied to the applicable person or entity, and in accordance with any amendments or revisions thereof. This includes, but is not limited to HIPAA, CMIA, 42 CFR "Part 2", and False Claims Act. (See Exhibit A – HIPAA Business Associate Agreement, to which the Parties agree to the set forth terms and conditions attached hereto and incorporated herein by reference).

8. Permits and Licenses:

Primary certifies that it possesses and shall continue to maintain or shall cause to be obtained and maintained, at no cost to County, all approvals, permissions, permits, licenses, and other forms of documentation required for it and its employees to comply with all existing foreign or domestic statutes, ordinances, and regulations, or other laws, that may be applicable to performance of services hereunder. County reserves the right to reasonably request and review all such applications, permits, and licenses prior to the commencement of any services hereunder.

9. Governing Law:

This MOA shall be governed, interpreted, construed, and enforced in accordance with the laws of the State of California.

10. Third Party Beneficiaries Excluded:

This MOA is intended solely for the benefit of the Parties listed herein. Any benefit to any third party is incidental and does not confer on any third party to this MOA any rights whatsoever regarding the performance of this MOA. Any attempt to enforce provisions of this MOA by third parties is specifically prohibited.

11. Amendments to Agreement:

Any Party may propose amendments to this MOA by providing written notice of such amendments to the other Party. This MOA may only be amended by a written amendment signed by all parties.

12. Severability:

If any terms or provisions of this MOA or the application thereof to any person or circumstance shall, to any extent, be held invalid or unenforceable, the remainder of this MOA, or the application of such term and provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and every

other term and provision of this MOA shall be valid and enforced to the maximum extent permitted by law.

13. Term:

The terms of this MOA shall commence on the date of the last signature affixed to this MOA and shall continue for a period of five (5) years, unless earlier terminated by either Party. If the Parties wish to extend this Agreement, they may do so by reviewing, updating, and reauthorizing this Agreement, in writing for additional periods not to exceed a five (5) year term.

14. Full Agreement:

This MOA represents the full and entire agreement between the Parties and supersedes any prior written or oral agreements that may have existed.

15. Scope of Agreement:

This MOA only applies to the program described herein and does not set forth any additional, current, or future obligations or agreements between the parties, except that the Parties may by written amendment amend the scope of this agreement.

16. Counterparts:

This MOA may be executed in any number of separate counterparts, each of which shall be deemed an original but all of which when taken together shall constitute one and the same instrument.

17. No Monetary Obligation:

There shall be no monetary obligation on County or Primary, one to the other.

18. Nondiscrimination:

County hereby notifies Primary that County's Unlawful Discrimination Ordinance (Article XIII of Chapter 2 of the Santa Barbara County Code) applies to this MOA and is incorporated herein by this reference with the same force and effect as if the ordinance were specifically set out herein and Primary's agrees to comply with said ordinance.

19. Authority:

All Parties to this MOA warrant and represent that they have the power and authority to enter into this MOA in the names, titles and capacities herein stated and on behalf of any entities, persons, or firms represented or purported to be represented by such entity(ies), person(s), or firm(s) and that all formal requirements necessary or required by any state and/or federal law in order to enter into this MOA have been fully complied with. Furthermore, by entering into this MOA, Primary hereby warrants that it shall not have

breached the terms or conditions of any other contract or agreement to which Primary is obligated, which breach would have a material effect hereon.

Agreement for Services of Independent Contractor between the **County of Santa Barbara** and **Primary Diagnostic, Inc.**

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective on May 6, 2025.

RECOMMENDED FOR APPROVAL:

Mouhanad Hammami, Director
Public Health Department

By: _____
Department Head

APPROVED AS TO FORM:

Rachel Van Mullem
County Counsel

By: _____
Deputy County Counsel

APPROVED AS TO FORM:

Greg Milligan, ARM
Risk Manager

By: _____
Risk Management

Agreement for Services of Independent Contractor between the **County of Santa Barbara** and **Primary Diagnostic, Inc.**

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective on May 6, 2025.

Primary Diagnostic, Inc.

By: _____
Authorized Representative

Name: Andrew Kobylinski _____

Title: CEO, Primary Diagnostics Inc. _____

EXHIBIT A
HIPAA BUSINESS ASSOCIATE AGREEMENT
(BAA)

This Business Associate Agreement ("BAA") supplements and is made a part of the Agreement between COUNTY (referred to herein as "Covered Entity") and CONTRACTOR (referred to herein as "Business Associate").

RECITALS

Covered Entity wishes to disclose certain information to Business Associate pursuant to the terms of the Agreement, some of which may constitute Protected Health Information ("PHI") (defined below).

Covered Entity and Business Associate intend to protect the privacy and provide for the security of PHI disclosed to Business Associate pursuant to the Agreement in compliance with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("HITECH Act"), and 45 CFR Parts 160 and 164, Subpart C (the "Security Rule"), Subpart D (the "Data Breach Notification Rule") and Subpart E (the "Privacy Rule") (collectively, the "HIPAA Regulations").

As part of the HIPAA Regulations, the Privacy Rule and the Security Rule (defined below) require Covered Entity to enter into a contract containing specific requirements with Business Associate prior to the disclosure of PHI, as set forth in, but not limited to, Title 45, Sections 164.314(a), 164.502(e) and 164.504(e) of the Code of Federal Regulations (C.F.R.) and contained in this BAA.

In consideration of the mutual promises below and the exchange of information pursuant to this BAA, the parties agree as follows:

1. Definitions

- a. **Breach** shall have the meaning given to such term under the HITECH Act [42 U.S.C. Section 17921].
- b. **Business Associate** shall have the meaning given to such term under the Privacy Rule, the Security Rule, and the HITECH Act, including but not limited to, 42 U.S.C. Section 17938 and 45 C.F.R. Section 160.103.
- c. **Covered Entity** shall have the meaning given to such term under the Privacy Rule and the Security Rule, including, but not limited to, 45 C.F.R. Section 160.103.
- d. **Data Aggregation** shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- e. **Designated Record Set** shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- f. **Electronic Protected Health Information** means Protected Health Information

that is maintained in or transmitted by electronic media.

- g. **Electronic Health Record** shall have the meaning given to such term in the HITECH Act, including, but not limited to, 42 U.S.C. Section 17921.
- h. **Health Care Operations** shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501.
- i. **Privacy Rule** shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and E.
- j. **Protected Health Information or PHI** means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual, and shall have the meaning given to such term under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.501. Protected Health Information includes Electronic Protected Health Information [45 C.F.R. Sections 160.103, 164.501].
- k. **Protected Information** shall mean PHI provided by Covered Entity to Business Associate or created or received by Business Associate on Covered Entity's behalf.
- l. **Security Rule** shall mean the HIPAA Regulation that is codified at 45 C.F.R. Parts 160 and 164, Subparts A and C.
- m. **Unsecured PHI** shall have the meaning given to such term under the HITECH Act and any guidance issued pursuant to such Act including, but not limited to, 42 U.S.C. Section 17932(h).

2. Obligations of Business Associate

- a. **Permitted Uses.** Business Associate shall not use Protected Information except for the purpose of performing Business Associate's obligations under the Agreement and as permitted under the Agreement and this BAA. Further, Business Associate shall not use Protected Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act if so used by Covered Entity. However, Business Associate may use Protected Information (i) for the proper management and administration of Business Associate, (ii) to carry out the legal responsibilities of Business Associate, or (iii) for Data Aggregation purposes for the Health Care Operations of Covered Entity [45 C.F.R. Sections 164.504(e)(2)(ii)(A) and 164.504(e)(4)(i)].
- b. **Permitted Disclosures.** Business Associate shall not disclose Protected Information except for the purpose of performing Business Associate's obligations under the Agreement and as permitted under the Agreement and this BAA. Business Associate shall not disclose Protected Information in any manner that would constitute a violation of the Privacy Rule or the HITECH Act if so disclosed by Covered Entity. However, Business Associate may disclose Protected Information (i) for the proper management and administration of Business Associate; (ii) to carry out the legal responsibilities of Business Associate; (iii) as

required by law; or (iv) for Data Aggregation purposes for the Health Care Operations of Covered Entity. If Business Associate discloses Protected Information to a third party, Business Associate must obtain, prior to making any such disclosure, (i) reasonable written assurances from such third party that such Protected Information will be held confidential as provided pursuant to this BAA and only disclosed as required by law or for the purposes for which it was disclosed to such third party, and (ii) a written agreement from such third party to immediately notify Business Associate of any breaches of confidentiality of the Protected Information, to the extent the third party has obtained knowledge of such breach [42 U.S.C. Section 17932; 45 C.F.R. Sections 164.504(e)(2)(i), 164.504(e)(2)(i)(B), 164.504(e)(2)(ii)(A) and 164.504(e)(4)(ii)].

- c. **Prohibited Uses and Disclosures.** Business Associate shall not use or disclose Protected Information for fundraising or marketing purposes. Business Associate shall not disclose Protected Information to a health plan for payment or health care operations purposes if the patient has requested this special restriction, and has paid out of pocket in full for the health care item or service to which the PHI solely relates [42 U.S.C. Section 17935(a)]. Business Associate shall not directly or indirectly receive remuneration in exchange for Protected Information, except with the prior written consent of Covered Entity and as permitted by the HITECH Act, 42 U.S.C. section 17935(d)(2); however, this prohibition shall not affect payment by Covered Entity to Business Associate for services provided pursuant to the Agreement. Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of this Agreement, the BAA, or the HIPAA Regulations.
- d. **Appropriate Safeguards.** Business Associate shall implement appropriate safeguards as are necessary to prevent the use or disclosure of Protected Information otherwise than as permitted by the Agreement or this BAA, including, but not limited to, administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Protected Information, in accordance with 45 C.F.R. Sections 164.308, 164.310, and 164.312. [45 C.F.R. Section 164.504(e)(2)(ii)(B); 45 C.F.R. Section 164.308(b)]. Business Associate shall comply with the policies and procedures and documentation requirements of the HIPAA Security Rule, including, but not limited to, 45 C.F.R. Section 164.316 [42 U.S.C. Section 17931].
- e. **Reporting of Improper Access, Use or Disclosure.** Business Associate shall report to Covered Entity in writing of any access, use or disclosure of Protected Information not permitted by the Agreement and this BAA, and any Breach of Unsecured PHI, as required by the Data Breach Notification Rule, of which it becomes aware without unreasonable delay and in no case later than five (5) business days after discovery [42 U.S.C. Section 17921; 45 C.F.R. Section 164.504(e)(2)(ii)(C); 45 C.F.R. Section 164.308(b)].
- f. **Business Associate's Subcontractors and Agents.** Business Associate shall ensure that any agents and subcontractors to whom it provides Protected Information,

agree in writing to the same restrictions and conditions that apply to Business Associate with respect to such PHI and implement the safeguards required by paragraph (d) above with respect to Electronic PHI [45 C.F.R. Section 164.504(e)(2)(ii)(D); 45 C.F.R. Section 164.308(b)]. Business Associate shall implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation (see 45 C.F.R. Sections 164.530(t) and 164.530(e)(l)).

- g. **Access to Protected Information.** To the extent that the Covered Entity keeps a designated record set then Business Associate shall make Protected Information maintained by Business Associate or its agents or subcontractors in Designated Record Sets available to Covered Entity for inspection and copying within five (5) days of a request by Covered Entity to enable Covered Entity to fulfill its obligations under state law [Health and Safety Code Section 123110] and the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.524 [45 C.F.R. Section 164.504(e)(2)(ii)(E)]. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act, including, but not limited to, 42 U.S.C. Section 17935(e).
- h. **Amendment of PHI for Business Associate who is Required to Maintain a Record Set.** If Business Associate is required to maintain a designated record set on behalf of the Covered Entity the Business Associate shall within ten (10) days of receipt of a request from Covered Entity for an amendment of Protected Information or a record about an individual contained in a Designated Record Set, Business Associate or its agents or subcontractors shall make such Protected Information available to Covered Entity for amendment and incorporate any such amendment to enable Covered Entity to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.526. If any individual requests an amendment of Protected Information directly from Business Associate or its agents or subcontractors, Business Associate must notify Covered Entity in writing within five (5) days of the request. Any approval or denial of amendment of Protected Information maintained by Business Associate or its agents or subcontractors shall be the responsibility of Covered Entity [45 C.F.R. Section 164.504(e)(2)(ii)(F)].
- i. **Accounting Rights.** Within ten (10) days of notice by Covered Entity of a request for an accounting of disclosures of Protected Information, Business Associate and its agents or subcontractors shall make available to Covered Entity the information required to provide an accounting of disclosures to enable Covered Entity to fulfill its obligations under the Privacy Rule, including, but not limited to, 45 C.F.R. Section 164.528, and the HITECH Act, including but not limited to 42 U.S.C. Section 17935(c), as determined by Covered Entity. Business Associate agrees to implement a process that allows for an accounting to be collected and maintained by Business Associate and its agents or subcontractors for at least six (6) years prior to the request. However, accounting of disclosures from an Electronic Health Record for treatment, payment or health care operations

purposes are required to be collected and maintained for only three (3) years prior to the request, and only to the extent that Business Associate maintains an electronic health record and is subject to this requirement. At a minimum, the information collected and maintained shall include: (i) the date of disclosure; (ii) the name of the entity or person who received Protected Information and, if known, the address of the entity or person; (iii) a brief description of Protected Information disclosed and (iv) a brief statement of purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure. In the event that the request for an accounting is delivered directly to Business Associate or its agents or subcontractors, Business Associate shall within five (5) days of a request forward it to Covered Entity in writing. It shall be Covered Entity's responsibility to prepare and deliver any such accounting requested. Business Associate shall not disclose any Protected Information except as set forth in Sections 2.b. of this BAA [45 C.F.R. Sections 164.504(e)(2)(ii)(G) and 165.528]. The provisions of this subparagraph shall survive the termination of this Agreement.

- j. **Governmental Access to Records.** Business Associate shall make its internal practices, books and records relating to the use and disclosure of Protected Information available to Covered Entity and to the Secretary of the U.S. Department of Health and Human Services (Secretary) for purposes of determining Business Associate's compliance with the Privacy Rule [45 C.F.R. Section 164.504(e)(2)(ii)(H)]. Business Associate shall provide to Covered Entity a copy of any Protected Information that Business Associate provides to the Secretary concurrently with providing such Protected Information to the Secretary.
- k. **Minimum Necessary.** Business Associate (and its agents or subcontractors) shall request, use and disclose only the minimum amount of Protected Information necessary to accomplish the purpose of the request, use, or disclosure [42 U.S.C. Section 17935(b); 45 C.F.R. Section 164.514(d)(3)]. Business Associate understands and agrees that the definition of "minimum necessary" is in flux and shall keep itself informed of guidance issued by the Secretary with respect to what constitutes "minimum necessary."
- l. **Data Ownership.** Business Associate acknowledges that Business Associate has no ownership rights with respect to the Protected Information.
- m. **Business Associate's Insurance.** Business Associate represents and warrants that it purchases commercial insurance to cover its exposure for any claims, damages or losses arising as a result of a breach of the terms of this BAA.
- n. **Notification of Possible Breach.** During the term of the Agreement, Business Associate shall notify Covered Entity within twenty-four (24) hours of any suspected or actual breach of security, or any access, use or disclosure of Protected Information not permitted by the Agreement or this BAA or unauthorized use or disclosure of PHI of which Business Associate becomes aware and/or any actual or suspected use or disclosure of data in violation of any applicable federal or state laws or regulations. Business Associate shall take

- (i) prompt corrective action to cure any such deficiencies and (ii) any action pertaining to such unauthorized disclosure required by applicable federal and state laws and regulations. [42 U.S.C. Section 17921; 45 C.F.R. Section 164.504(e)(2)(ii)(C); 45 C.F.R. Section 164.308(b)]
- o. **Breach Pattern or Practice by Covered Entity.** Pursuant to 42 U.S.C. Section 17934(b), if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material breach or violation of the Covered Entity's obligations under the Agreement or this BAA or other arrangement, the Business Associate must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, the Business Associate must terminate the Agreement or other arrangement if feasible, or if termination is not feasible, report the problem to the Secretary. Business Associate shall provide written notice to Covered Entity of any pattern of activity or practice of the Covered Entity that Business Associate believes constitutes a material breach or violation of the Covered Entity's obligations under the Agreement or this BAA or other arrangement within five (5) days of discovery and shall meet with Covered Entity to discuss and attempt to resolve the problem as one of the reasonable steps to cure the breach or end the violation.
 - p. **Audits, Inspection and Enforcement.** Within ten (10) days of a written request by Covered Entity, Business Associate and its agents or subcontractors shall allow Covered Entity to conduct a reasonable inspection of the facilities, systems, books, records, agreements, policies and procedures relating to the use or disclosure of Protected Information pursuant to this BAA for the purpose of determining whether Business Associate has complied with this BAA; provided, however, that (i) Business Associate and Covered Entity shall mutually agree in advance upon the scope, timing and location of such an inspection, (ii) Covered Entity shall protect the confidentiality of all confidential and proprietary information of Business Associate to which Covered Entity has access during the course of such inspection; and (iii) Covered Entity shall execute a nondisclosure agreement, upon terms mutually agreed upon by the parties, if requested by Business Associate. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems, books, records, agreements, policies and procedures does not relieve Business Associate of its responsibility to comply with this BAA, nor does Covered Entity's (i) failure to detect or (ii) detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices, constitute acceptance of such practice or a waiver of Covered Entity's enforcement rights under the Agreement or this BAA, Business Associate shall notify Covered Entity within ten (10) days of learning that Business Associate has become the subject of an audit, compliance review, or complaint investigation by the Office for Civil Rights.
 - q. **Compliance with HIPAA Workforce Training.** As set forth in section 164.530 of 45CFR Business Associate is expected to adhere to the Health Insurance Portability and Accountability Act (HIPAA) regulations to the extent necessary to

comply with Covered Entity's legal obligations and to develop and maintain comprehensive consumer confidentiality policies and procedures, provide annual training of all affected staff regarding those policies and procedures including Security and Privacy safeguards, and demonstrate reasonable effort to secure written and/or electronic data to document the provision of such training and agrees to make available to the Covered Entity upon request. The parties should anticipate that this agreement will be modified as necessary for full compliance with HIPAA.

3. Termination

- a. **Material Breach.** A breach by Business Associate of any provision of this BAA, as determined by Covered Entity, shall constitute a material breach of the Agreement and shall provide grounds for immediate termination of the Agreement, any provision in the Agreement to the contrary notwithstanding [45 C.F.R. Section 164.504(e)(2)(iii)].
- b. **Judicial or Administrative Proceedings.** Covered Entity may terminate the Agreement, effective immediately, if (i) Business Associate is named as a defendant in a criminal proceeding for a violation of HIPAA, the HITECH Act, the HIPAA Regulations or other security or privacy laws or (ii) a finding or stipulation that the Business Associate has violated any standard or requirement of HIPAA, the HITECH Act, the HIPAA Regulations or other security or privacy laws is made in any administrative or civil proceeding in which the party has been joined.
- c. **Effect of Termination.** Upon termination of the Agreement for any reason, Business Associate shall, at the option of Covered Entity, return or destroy all Protected Information that Business Associate or its agents or subcontractors still maintain in any form, and shall retain no copies of such Protected Information. If return or destruction is not feasible, as determined by Covered Entity, Business Associate shall continue to extend the protections of Section 2 of this BAA to such information, and limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. [45 C.F.R. Section 164.504(e)(ii)(2)(I)]. If Covered Entity elects destruction of the PHI, Business Associate shall certify in writing to Covered Entity that such PHI has been destroyed.

4. Indemnification

If Business Associate fails to adhere to any of the privacy, confidentiality, and/or data security provisions set forth in this BAA or if there is a Breach of PHI in Business Associate's possession and, as a result, PHI or any other confidential information is unlawfully accessed, used or disclosed, Business Associate agrees to reimburse Covered Entity for any and all costs, direct or indirect, incurred by Covered Entity associated with any Breach notification obligations. Business Associate also agrees to pay for any and all fines and/or administrative penalties imposed for such unauthorized access, use or disclosure of confidential information or for delayed reporting if it fails to notify the Covered Entity of the Breach as required by this BAA.

5. Disclaimer

Covered Entity makes no warranty or representation that compliance by Business Associate with this BAA, HIPAA, the HITECH Act, or the HIPAA Regulations will be adequate or satisfactory for Business Associate's own purposes. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

6. Certification

To the extent that Covered Entity determines that such examination is necessary to comply with Covered Entity's legal obligations pursuant to HIPAA relating to certification of its security practices, Covered Entity or its authorized agents or contractors, may, at Covered Entity's expense, examine Business Associate's facilities, systems, procedures and records as may be necessary for such agents or contractors to certify to Covered Entity the extent to which Business Associate's security safeguards comply with HIPAA, the HITECH Act, the HIPAA Regulations or this BAA.

7. Amendment to Comply with Law

The parties acknowledge that state and federal laws relating to data security and privacy are rapidly evolving and that amendment of the Agreement or this BAA may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act, the Privacy Rule, the Security Rule and other applicable laws relating to the security or confidentiality of PHI. The parties understand and agree that Covered Entity must receive satisfactory written assurance from Business Associate that Business Associate will adequately safeguard all Protected Information. Upon the request of either party, the other party agrees to promptly enter into negotiations concerning the terms of an amendment to this BAA embodying written assurances consistent with the standards and requirements of HIPAA, the HITECH Act, the Privacy Rule, the Security Rule or other applicable laws. Covered Entity may terminate the Agreement upon thirty (30) days written notice in the event (i) Business Associate does not promptly enter into negotiations to amend the Agreement or this BAA when requested by Covered Entity pursuant to this Section or (ii) Business Associate does not enter into an amendment to the Agreement or this BAA providing assurances regarding the safeguarding of PHI that Covered Entity, in its sole discretion, deems sufficient to satisfy the standards and requirements of applicable laws.

8. Assistance in Litigation of Administrative Proceedings

Business Associate shall make itself, and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under the Agreement or this BAA, available to Covered Entity, at no cost to Covered Entity, to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against Covered Entity, its directors, officers or employees based upon a claimed violation of HIPAA, the HITECH Act, the Privacy Rule, the Security Rule, or other laws relating to security and privacy, except where Business Associate or its subcontractor, employee or agent is named adverse party.

9. No Third-Party Beneficiaries

Nothing express or implied in the Agreement or this BAA is intended to confer, nor shall anything herein confer, upon any person other than Covered Entity, Business Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

10. Effect on Agreement

Except as specifically required to implement the purposes of this BAA, or to the extent inconsistent with this BAA, all other terms of the Agreement shall remain in force and effect.

11. Entire Agreement of the Parties

This BAA supersedes any and all prior and contemporaneous business associate agreements between the parties and constitutes the final and entire agreement between the parties hereto with respect to the subject matter hereof. Covered Entity and Business Associate acknowledge that no representations, inducements, promises, or agreements, oral or otherwise, with respect to the subject matter hereof, have been made by either party, or by anyone acting on behalf of either party, which are not embodied herein. No other agreement, statement or promise, with respect to the subject matter hereof, not contained in this BAA shall be valid or binding.

12. Interpretation

The provisions of this BAA shall prevail over any provisions in the Agreement that may conflict or appear inconsistent with any provision in this BAA. This BAA and the Agreement shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule. The parties agree that any ambiguity in this BAA shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act, the Privacy Rule and the Security Rule.