



Maine Department of Health and Human Services Business Associate Agreement

This Business Associate Agreement (“Agreement”) is made this ____ day of _____, 20____ (the “Effective Date”) by and between the State of Maine, Department of Health and Human Services (the Covered Entity, hereinafter, the “Department”) and _____ (“Business Associate”), together (the “Parties”); and

WHEREAS, Business Associate may use, disclose, create, receive, maintain or transmit protected health information in a variety of form or formats, including verbal, paper and electronic (together, “PHI”) on behalf of the Department in connection with Business Associate’s performance of its obligations under the following agreement between the parties:

_____ dated _____, 20____ (the “Underlying Agreement”); and

WHEREAS, the Parties intend to ensure the confidentiality, privacy and security of Department’s PHI as required by law, including the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191 (HIPAA), and its implementing regulations at 45 CFR Parts 160 and 164 (the Privacy, Security, Breach Notification and Enforcement Rules or “HIPAA Rules”) as updated by the Health Information Technology for Economic and Clinical Care Act (HITECH) enacted under Title XII of the American Recovery and Reinvestment Act of 2009, and its implementing Regulations (together, the “HIPAA and HITECH Rules”); and

WHEREAS, the Parties agree that certain federal and state laws, rules, regulations and accreditation standards also impose confidentiality restrictions that apply to this business relationship, and may include, but are not limited to: 42 CFR 2 *et. seq.*; 5 M.R.S.A. §19203-D; 22 M.R.S.A. §§42, 261, 815, 824, 833, 1494, 1596, 1711-C, 1828, 3173, 3292, 4008, 5328, 7250, 7703, 8754; 10 M.R.S.A 1346 *et. seq.*; 34-B M.R.S.A. §1207; 14-193 C.M.R, Ch. 1, Part A, § IX; and applicable accreditation standards of The Joint Commission or other appropriate accreditation body regarding confidentiality.

NOW THEREFORE, the parties agree as follows:

Specific Definitions for the Purpose of this Agreement:

Breach means the unauthorized acquisition, access, use or disclosure of PHI that compromises the security or privacy of such PHI. A security or privacy incident that involves PHI is presumed to be a breach requiring notification unless the Department proves, through specific risk analysis steps, that there is a low probability that the PHI was compromised or a) the incident does not involved unsecured PHI, or b) the incident falls into another exception or safe harbor as set forth in the HIPAA and HITECH Rules.

Business Associate is a person or entity that creates, receives, maintains or transmits PHI on behalf of, or provides services to, a covered entity, as set forth in the HIPAA Rules and other than in the capacity of a workforce member.

Covered Entity is a 1) health plan, (2) health care clearinghouse, or 3) health care provider who electronically transmits any health information in connection with transactions for which HHS has adopted standards. Generally, these electronic transactions concern billing and payment for services or insurance coverage.

Designated Record Set means the billing and medical records about individuals maintained by or for a covered provider: the enrollment, claims adjudication, payment, case or medical management record systems maintained by or for a health plan; or that are used in whole, or in part, by the covered entity to make decisions about individuals.

Individual means the person who is the subject of the PHI.

Protected Health Information means information that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse that relates to the past, present, or future physical or mental health or 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 is transmitted or maintained in electronic or any other form or medium.

Security Incident means the attempted or successful unauthorized access, use, disclosure, modification or destruction of information [or PHI] or interference with system operation in an information system.

Subcontractor means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private, to whom a business associate has delegated a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

Unsecured Protected Health Information means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the U.S. Department of Health and Human Services (“HHS”) in its guidance.

General Definitions. The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA and HITECH Rules: Data Aggregation, Disclosure, Health Care Operations, Minimum Necessary, Notice of Privacy Practices, Required by Law, and Use.

1. Permitted Uses and Disclosures

- a. Business Associate agrees to use or disclose the PHI authorized by this Agreement only to perform the services of the Underlying Agreement between the Parties, or as required by law.
- b. Business Associate may use or disclose PHI for the proper management and administration of Business Associate or to carry out the legal responsibilities of the Business Associate, only where a) the use or disclosure does not violate any law governing the protection of the PHI, including, but not limited to, prohibitions under 42 CFR Part 2 (Part 2 Regulations), and b) the disclosures are required by law or c) Business Associate agrees only to disclose the minimum necessary PHI to accomplish the intended purpose and i) obtains reasonable assurances from the person or entity to whom the information is disclosed that the PHI will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person or entity, and ii) the person or entity agree to immediately notify Business Associate of any instances of which it is aware that the confidentiality, privacy or security of the information has been actually or potentially breached.
- c. Business Associate may provide data aggregation services relating to the health care operations of the Department, or de-identify the Department's PHI, only when such specific services are permissible under the Underlying Agreement or as otherwise preapproved in writing by the Department.

2. Obligations and Activities of the Business Associate

- a. *Compliance.* Business Associate agrees to comply with the HIPAA and HITECH Rules, and other applicable state or federal law, to ensure the protection of the Department's PHI, and only use and disclose PHI consistent with the Department's minimum necessary policy and the legal requirements of this Agreement. Business Associate may not use or disclose PHI in a manner that would violate the HIPAA or HITECH Rules or other state or federal law if performed by the Department.
- b. *Safeguards.* In complying with the HIPAA and HITECH Rules, Business Associate agrees to use appropriate administrative, technical and physical safeguards, and comply with any required security or privacy obligations, to protect the confidentiality, integrity and availability of the Department's PHI.
- c. *Reporting.* Business Associate agrees to report to the Department any inappropriate use or disclosure of the Department's PHI of which it becomes aware, i.e. any use or disclosure not permitted in this Agreement or in violation of any legal requirement, including actual and suspected breaches of unsecured PHI, and any actual or potential security incident of which it becomes aware. Such report will be made to the

Department's Director of Healthcare Privacy or her designee within twenty-four (24) hours of when the Business Associate becomes aware of an actual or suspected incident or breach. In the event that a breach is determined to have occurred under the authority of the Business Associate, Business Associate will cooperate promptly with the Department to provide all specific information required by the Department for mandatory notification purposes.

- d. *Subcontractors and Agents.* In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, Business Associate shall ensure that any third parties, agents or subcontractors (together, "Subcontractors") that use, disclose, create, acquire, receive, maintain, or transmit PHI on behalf of Business Associate agree to the same restrictions, conditions, and requirements that apply to Business Associate with respect to such PHI. Business Associate shall obtain and maintain a written agreement with each Subcontractor that has or will have access, through Business Associate, to the Department's PHI, ensuring that the Subcontractor agrees to be bound to the same restrictions, terms and conditions that apply to Business Associate under this Agreement.
- e. *Mitigation.* The Business Associate shall exhaust, at its sole expense, all reasonable efforts to mitigate any harmful effect known to the Business Associate arising from the use or disclosure of PHI by Business Associate in violation of the terms of this Agreement.
- f. *Accounting of Disclosures.* To the extent required by the terms of this Agreement, Business Associate will maintain and make available the information and/or documentation required to provide an accounting of disclosures as necessary to satisfy the Department's obligations under 45 CFR 164.528.
- g. *Access.* In the event that Business Associate creates or maintains PHI in a designated record set, Business Associate will use commercially reasonable efforts to make PHI available in the format requested, and as necessary to satisfy the Department's obligation under 45 C.F.R. 164.524, within 30 days from the time of request. Business Associate will inform the Department of the individual's request within 5 (five) business days of the request.
- h. *Amendment.* In the event that Business Associate creates or maintains PHI in a designated record set, Business Associate agrees to make any amendment(s) to the PHI as directed or agreed to by the Department, or take other measures as necessary to satisfy the Department's obligations under 45 CFR 164.526, in such time period and in such manner as the Department may direct.
- i. *Restrictions.* Upon notification from the Department, Business Associate shall adhere to any restrictions on the use or disclosure of PHI agreed to by or required of the Department pursuant to 45 CFR 164.522.
- j. *Audit by the Department or the HHS Secretary.* The Business Associate will make its internal practices, books and records relating to the use or disclosure of PHI received

from the Department or used, acquired, maintained, created or received by the Business Associate on behalf of the Department, available to either the Department or the HHS Secretary for the purposes of determining the compliance of either the Department or the Business Associate with the Medicaid Act, and the HIPAA and HITECH Rules, or any other federal, state or accreditation requirement. 45 C.F.R. 164.504.

- k. *Other Obligations:* To the extent that Business Associate is to carry out one or more of the Department's obligations under the HIPAA and HITECH Rules or other federal or state law, Business Associate agrees to comply with the legal requirements that apply to the Department in performing that obligation;

3. Obligations of the Department

- a. The Department shall notify Business Associate of a) any limitation in any applicable Notice of Privacy Practices that would affect the use or disclosure of PHI by the Business Associate and b) any changes, revocations, restrictions or permissions by an individual to the use and disclosure of his/her PHI to which the Department has agreed, to the extent such restrictions or limitations may affect the performance of Business Associate's services on behalf of the Department.
- b. The Department shall not request that Business Associate use or disclose PHI in any format, and in any manner, that would be prohibited if performed by the Department.

4. Hold Harmless

Business Associate agrees to indemnify and hold harmless the Department, its directors, officers, agents, shareholders, and employees against any and all claims, demands, expenses, liabilities or causes of action that arise from any use or disclosure of PHI not specifically permitted by this Agreement, applicable state or federal laws, licensing, accreditation or other requirements.

5. Term of Agreement

- a. *Term.* This Agreement shall be effective as of the Effective Date and shall terminate at the end of the term of the Underlying Agreement. To the extent that the Underlying Agreement automatically renews, this Agreement shall also automatically renew itself for the same renewal period unless the Department terminates this Agreement for cause as set forth in Section 5(c). Either party may terminate the Agreement consistent with the written notice provision regarding termination in the Underlying Agreement.
- b. *Auto-renewal.* In the event that this Agreement is automatically renewed, the Business Associate agrees to be bound by the terms of this Agreement and laws referenced in this Agreement that are current and in effect at the time of renewal.
- c. *Termination for Cause.* Notwithstanding the foregoing, Business Associate authorizes termination of this Agreement by the Department if the Department determines that Business Associate has violated a material term of the Agreement. The Department shall either, at its sole discretion:

- i. Provide the Business Associate an opportunity to cure or end the violation within a time frame and upon such conditions as established by the Department; and
 - ii. Immediately terminate this Agreement in the event the Business Associate has either failed to cure in the time frame provided by the Department or if cure is not possible.
 - d. *Obligations of the Business Associate upon Termination.* Upon termination of this Agreement for any reason, Business Associate, shall
 - i. Return or destroy all PHI used, created, accessed, acquired, maintained, or received by the Business Associate on behalf of the Department, and retain no copies in any format. Business Associate shall ensure that its Subcontractors do the same.
 - ii. If the Department agrees that Business Associate may destroy all PHI in its possession, Business Associate shall certify such destruction to the Department.
 - iii. If returning or destroying PHI is not feasible, Business Associate agrees to protect the confidentiality of the PHI and retain only that PHI which is necessary for the Business Associate to continue its proper management and administration, or to carry out its legal responsibilities. Business Associate shall not use or disclose the PHI for other than the purpose for which it was retained, and return to the Department, or destroy if approved by the Department, such PHI when no longer required. Furthermore, Business Associate shall continue to use appropriate safeguards and comply with the HIPAA and HITECH Rules, other applicable state and federal law, with respect to PHI in any format for as long as Business Associate retains the PHI.
 - iv. Upon appropriate direction from the Department, Business Associate shall transmit the PHI to another business associate of the Department consistent with all legal and regulatory safeguards delineated in this Agreement.

6. Qualified Service Organization Agreement

To the extent that in performing its services for or on behalf of the Department, Business Associate uses, discloses, maintains or transmits PHI that is protected by the Part 2 Regulations, Business Associate acknowledges that it is a Qualified Service Organization for the purpose of such federal law; acknowledges that in receiving, storing, processing or otherwise dealing with any such patient records, it is fully bound by the Part 2 Regulations; and, if necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the Part 2 Regulations.

7. Survival of Business Associate Obligations

The obligations of the Business Associate under this Agreement shall survive the termination of this Agreement indefinitely.

8. Miscellaneous

- a. *Amendment.* The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for the Department to comply with the requirements of the HIPAA and HITECH Rules, and/or other applicable laws or requirements. This Agreement may only be amended in writing, signed by authorized representatives of the Parties.
- b. *Injunction.* The Department and Business Associate agree that any violation of the provisions of this Addendum may cause irreparable harm to the Department. Accordingly, in addition to any other remedies available to the Department, Department shall be entitled to seek an injunction or other decree of specific performance with respect to any violation of this Agreement or explicit threat thereof, without bond or other security being required and without the necessity of demonstrating actual damages.
- c. *Interpretation.* Any ambiguity in this Agreement shall be resolved to ensure that the Department is in compliance with the HIPAA and HITECH Rules, or other applicable laws or privacy or security requirements.
- d. *Legal References.* A reference in this Agreement to a section in the HIPAA or HITECH Rules or to other federal or state law, means the section as in effect or as amended.

IN WITNESS WHEREOF, the parties have executed this Business Associate Agreement as of the Effective Date.

| | Department | | Business Associate |
|------------|--------------------------------|------------|--------------------|
| Signature: | _____ | Signature: | _____ |
| Name: | _____ | Name: | _____ |
| Title: | <u>Chief Operating Officer</u> | Title: | _____ |
| Date: | _____ | Date: | _____ |