

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the “Agreement”) is made by and among the _____, a unit of the Maryland Department of Health and Mental Hygiene (herein referred to as “Covered Entity”) and _____ (hereinafter known as “Business Associate”). Covered Entity and Business Associate shall collectively be known herein as the “Parties”.

WHEREAS, Covered Entity have a business relationship with Business Associate that is memorialized in a separate agreement (the “Underlying Agreement”) pursuant to which Business Associate may be considered a “business associate” of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996 including all pertinent regulations (45 CFR Parts 160 and 64), as amended from time to time, issued by the U.S. Department of Health and Human Services as either have been amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the “HITECH Act”), as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5) (collectively, “HIPAA”); and

WHEREAS, the nature of the contractual relationship between Covered Entity and Business Associate may involve the exchange of Protected Health Information (“PHI”) as that term is defined under HIPAA; and

WHEREAS, for good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this agreement for the purpose of ensuring compliance with the requirements of HIPAA and the Maryland Confidentiality of Medical Records Act (Md. Ann. Code, Health-General §§4-301 *et seq.*) (“MCMRA”); and

WHEREAS, this Agreement supersedes and replaces any and all Business Associate Agreements the Covered Entity and Business Associate may have entered into prior to the date hereof;

NOW THEREFORE, the premises having been considered and with acknowledgment of the mutual promises and of other good and valuable consideration herein contained, the Parties, intending to be legally bound, hereby agree as follows:

I. DEFINITIONS.

A. Individual. “Individual” shall have the same meaning as the term “individual” in 45 CFR §164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).

B. Breach. “Breach” shall have the same meaning as the term “breach” in 45 CFR § 164.402.

C. Designated Record Set. “Designated Record Set” shall have the same meaning as the term “designated record set” in 45 CFR §164.501.

D. Privacy Rule. “Privacy Rule” shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

E. Protected Health Information. “Protected Health Information” or “PHI” shall have the same meaning as the term “protected health information” in 45 CFR §164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

F. Required By Law. “Required By Law” shall have the same meaning as the term “required by law” in 45 CFR §164.501.

G. Secretary. “Secretary” shall mean the Secretary of the U.S. Department of Health and Human Services or his or her designee.

H. Unsecured Protected Health Information. “Unsecured Protected Health Information” or “Unsecured PHI” shall mean PHI that is not secured through the use of a technology or methodology specified by the Secretary in guidance or as otherwise defined in the §13402(h) of the HITECH Act.

II. USE OR DISCLOSURE OF PHI BY BUSINESS ASSOCIATE.

A. Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement, provided that such use or disclosure would not violate the Privacy Rule.

B. Business Associate shall only use and disclose PHI if such use or disclosure complies with each applicable requirement of 45 CFR §164.504(e).

C. Business Associate shall be directly responsible for full compliance with the relevant requirements of the Privacy Rule to the same extent as Covered Entity.

III. DUTIES OF BUSINESS ASSOCIATE RELATIVE TO PHI.

A. Business Associate shall not use or disclose PHI other than as permitted or required by this Agreement, the MCMRA, or as Required By Law.

B. Business Associate shall implement 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.

C. Business Associate shall immediately notify Covered Entity of any use or disclosure of PHI in violation of this Agreement

D. In addition to its obligations in Section III.C, Business Associate shall document and notify Covered Entity of a Breach of Unsecured PHI. Business Associate's notification to Covered Entity hereunder shall:

1. Be made to Covered Entity without unreasonable delay and in no case later than 50 calendar days after the incident constituting the Breach is first known, except where a law enforcement official determines that a notification would impede a criminal investigation or cause damage to national security. For purposes of clarity for this Section III.D.1, Business Associate must notify Covered Entity of an incident involving the acquisition, access, use or disclosure of PHI in a manner not permitted under 45 CFR Part E within 50 calendar days after an incident even if Business Associate has not conclusively determined within that time that the incident constitutes a Breach as defined by HIPAA;

2. Include the names of the Individuals whose Unsecured PHI has been, or is reasonably believed to have been, the subject of a Breach;

3. Be in substantially the same form as **Exhibit A** hereto; and

4. Include a draft letter for the Covered Entity to utilize to notify the Individuals that their Unsecured PHI has been, or is reasonably believed to have been, the subject of a Breach that includes, to the extent possible:

- a) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
- b) A description of the types of Unsecured PHI that were involved in the Breach (such as full name, Social Security number, date of birth, home address, account number, disability code, or other types of information that were involved);
- c) Any steps the Individuals should take to protect themselves from potential harm resulting from the Breach;
- d) A brief description of what the Covered Entity and the Business Associate are doing to investigate the Breach, to mitigate losses, and to protect against any further Breaches; and
- e) Contact procedures for Individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

E. In the event of an unauthorized use or disclosure of PHI or a Breach of Unsecured PHI, Business Associate shall mitigate, to the extent practicable, any harmful effects of said disclosure that are known to it.

F. Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.

G. To the extent applicable, Business Associate shall provide access to Protected Health Information in a Designated Record Set at reasonable times, at the request of Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR §164.524.

H. To the extent applicable, Business Associate shall make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 CFR §164.526 at the request of Covered Entity or an Individual.

I. Business Associate shall, upon request with reasonable notice, provide Covered Entity access to its premises for a review and demonstration of its internal practices and procedures for safeguarding PHI.

J. Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for a Covered Entity to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. §164.528. Should an individual make a request to Covered Entity for an accounting of disclosures of his or her PHI pursuant to 45 C.F.R. §164.528, Business Associate agrees to promptly provide Covered Entity with information in a format and manner sufficient to respond to the individual's request.

K. Business Associate shall, upon request with reasonable notice, provide Covered Entity with an accounting of uses and disclosures of PHI provided to it by Covered Entity.

L. Business Associate shall make its internal practices, books, records, and any other material requested by the Secretary relating to the use, disclosure, and safeguarding of PHI received from Covered Entity available to the Secretary for the purpose of determining compliance with the Privacy Rule. The aforementioned information shall be made available to the Secretary in the manner and place as designated by the Secretary or the Secretary's duly appointed delegate. Under this Agreement, Business Associate shall comply and cooperate with any request for documents or other information from the Secretary directed to Covered Entity that seeks documents or other information held by Business Associate.

M. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 42 C.F.R. §164.502(j)(1).

N. Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that disclosures

are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

IV. TERM AND TERMINATION.

A. Term. The Term of this Agreement shall be effective as of _____, and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section IV.

B. Termination for Cause. Upon Covered Entity's knowledge of a material breach of this Agreement by Business Associate, Covered Entity shall:

1. Provide an opportunity for Business Associate to cure the breach or end the violation and, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity, terminate this Agreement;

2. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or

3. If neither termination nor cure is feasible, report the violation to the Secretary.

C. Effect of Termination.

1. Except as provided in paragraph C(2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall not retain any copies of the Protected Health Information.

2. In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity written notification of the conditions that make return or destruction infeasible. After written notification that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

3. Should Business Associate make an intentional or grossly negligent Breach of PHI in violation of this Agreement or HIPAA or an intentional or grossly negligent disclosure of information protected by the MCMRA, Covered Entity shall have the right to immediately terminate any contract, other than this Agreement, then in force between the Parties, including the Underlying Agreement.

V. CONSIDERATION. Business Associate recognizes that the promises it has made in this Agreement shall, henceforth, be detrimentally relied upon by Covered Entity in choosing to continue or commence a business relationship with Business Associate.

VI. REMEDIES IN EVENT OF BREACH. Business Associate hereby recognizes that irreparable harm will result to Covered Entity, and to the business of Covered Entity, in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of breach of any of the covenants and assurances contained in Sections II or III above, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of Sections II or III. Furthermore, in the event of breach of Sections II or III by Business Associate, Covered Entity is entitled to reimbursement and indemnification from Business Associate for Covered Entity's reasonable attorneys' fees and expenses and costs that were reasonably incurred as a proximate result of Business Associate's breach. The remedies contained in this Section VI shall be in addition to (and not supersede) any action for damages and/or any other remedy Covered Entity may have for breach of any part of this Agreement.

VII. MODIFICATION; AMENDMENT. This Agreement may only be modified or amended through a writing signed by the Parties and, thus, no oral modification or amendment hereof shall be permitted. The Parties 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 the Privacy Rule and HIPAA.

VIII. INTERPRETATION OF THIS AGREEMENT IN RELATION TO OTHER AGREEMENTS BETWEEN THE PARTIES. Should there be any conflict between the language of this Agreement and any other contract entered into between the Parties (either previous or subsequent to the date of this Agreement), the language and provisions of this Agreement shall control and prevail unless the Parties specifically refer in a subsequent written agreement to this Agreement by its title and date and specifically state that the provisions of the later written agreement shall control over this Agreement.

IX. COMPLIANCE WITH STATE LAW. The Business Associate acknowledges that by accepting the PHI from Covered Entity, it becomes a holder of medical records information under the MCMRA and is subject to the provisions of that law. If the HIPAA Privacy or Security Rules and the MCMRA conflict regarding the degree of protection provided for protected health information, Business Associate shall comply with the more restrictive protection requirement.

X. MISCELLANEOUS.

A. Ambiguity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the Privacy Rule.

B. Regulatory References. A reference in this Agreement to a section in the Privacy Rule means the section as in effect or as amended.

C. Notice to Covered Entity. Any notice required under this Agreement to be given Covered Entity shall be made in writing to:

Ramiak James, Esq.
Privacy Officer and Compliance Analyst
Department of Health & Mental Hygiene
Office of the Inspector General
201 W. Preston Street, Floor 5
Baltimore, MD 21201-2301
Phone: (410) 767-5411

D. Notice to Business Associate. Any notice required under this Agreement to be given Business Associate shall be made in writing to:

Address: _____

Attention: _____

Phone: _____

IN WITNESS WHEREOF and acknowledging acceptance and agreement of the foregoing, the Parties affix their signatures hereto.

COVERED ENTITY:

BUSINESS ASSOCIATE:

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

EXHIBIT A
FORM OF NOTIFICATION TO COVERED ENTITY OF
BREACH OF UNSECURED PHI

**NOTIFICATION TO THE
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
ABOUT A
BREACH OF UNSECURED PROTECTED HEALTH INFORMATION**

This notification is made pursuant to Section IIID(3) of the Business Associate Agreement between:

- The Maryland Medical Assistance Program, a unit of the Maryland Department of Health and Mental Hygiene (DHMH), and
- _____ (Business Associate).

Business Associate hereby notifies DHMH that there has been a breach of unsecured (unencrypted) protected health information (PHI) that Business Associate has used or has had access to under the terms of the Business Associate Agreement.

Description of the breach: _____

Date of the breach: _____ Date of discovery of the breach: _____

Does the breach involve 500 or more individuals? Yes/No If yes, do the people live in multiple states? Yes/No

Number of individuals affected by the breach: _____

Names of individuals affected by the breach: _____

The types of unsecured PHI that were involved in the breach (such as full name, Social Security number, date of birth, home address, account number, or disability code): _____

Description of what Business Associate is doing to investigate the breach, to mitigate losses, and to protect against any further breaches: _____

Contact information to ask questions or learn additional information:

Name: _____

Title: _____

Address: _____

Email Address: _____

Phone Number: _____