This is only sample language. The language should be changed to accurately reflect business arrangements between a covered entity and business associate or business associate and subcontractor. In addition, these or similar provisions may be incorporated into an agreement for the provision of services between a covered entity and business associate or they may be incorporated into a separate business associate agreement. These provisions address only concepts and requirements set forth in the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules, and alone may not be sufficient to result in a binding contract under State law. They do not include many formalities and substantive provisions that may be required or typically included in a valid contract. Reliance on this sample does not replace consultation with a lawyer or negotiations between the parties to the contract.

Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these sample provisions.

### **BUSINESS ASSOCIATE AGREEMENT**

THIS AGREEMENT is made by and between	("Covered Entity"), a	
medical practice with a place of business at		
, a corporation/sole pr		
	, Maine 04XXX (enter zip) ("Business Associate").	
WITNESSET	Н:	
WHEREAS, Covered Entity wishes to retain the profess	ional services of Business Associate;	
WHEREAS, Business Associate wishes to provide such	services to Covered Entity;	
<b>WHEREAS</b> , Covered Entity is prepared to meet the priv federal law.	vacy standards established by state and	
NOW THEREFOR	RE,	
IN CONSIDERATION OF the mutual covenants contain	ined herein, the parties agree as follows:	
Definitions		
Catch-all definition:		
The following terms used in this Agreement shall have the HIPAA Rules: Breach, Data Aggregation, Designated R Operations, Individual, Minimum Necessary, Notice of I	ecord Set, Disclosure, Health Care	

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Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured

Protected Health Information, and Use.

Specific definitions:

- (a) <u>Business Associate</u>. "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Business Associate].
- (b) <u>Covered Entity</u>. "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Covered Entity medical practice or facility].
- (c) <u>HIPAA Rules</u>. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

### Obligations and Activities of Business Associate

Business Associate agrees to:

- (a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;
- (b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement;
- (c) To handle health information in compliance with Maine's confidentiality statute, 22 M.R.S.A. §1711-C;
- (d) Mitigate, to the extent practicable, any harmful effect that is known to the business associate of a use or disclosure of protected health information by the business associate that is violation of the HIPPA Rules, state law, or the requirements of this agreement;
- (e) Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware:

[The parties may wish to add additional specificity regarding the breach notification obligations of the business associate, such as a stricter timeframe for the business associate to report a potential breach to the covered entity and/or whether the business associate will handle breach notifications to individuals, the HHS Office for Civil Rights (OCR), and potentially the media, on behalf of the covered entity or whether the covered entity will make all notifications.]

(f) If applicable, in accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information;

- (g) Provide access, at the request of the covered entity, and in the time and manner designated by the covered entity, to any protected health information generated by the covered entity in its possession in order to enable the covered entity to comply with any obligations under the HIPAA Rules.
- (h) Make available protected health information to the [Choose either "covered entity" or "individual or the individual's designee"] as necessary to satisfy covered entity's obligations to provide individuals access to their protected health information under 45 CFR 164.524;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for access that the business associate receives directly from the individual - such as whether and in what time and manner a business associate is to provide the requested access or whether the business associate will forward the individual's request to the covered entity to fulfill - and the timeframe for the business associate to provide the information to the covered entity]

(i) Make any amendment(s) to protected health information as directed or agreed to by the covered entity pursuant to an individual's right to amend their records under 45 CFR 164.526, or take other measures as necessary to satisfy covered entity's obligations under 45 CFR 164.526;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for amendment that the business associate receives directly from the individual - such as whether and in what time and manner a business associate is to act on the request for amendment or whether the business associate will forward the individual's request to the covered entity- and the timeframe for the business associate to incorporate any amendments to the information in the designated record set. Unless the business associate maintains, possesses or controls access to medical records this request would typically be forwarded to the covered entity.]

(j) Maintain and make available the information required to provide an accounting of disclosures to the *[Choose either "covered entity" or "individual"]* as necessary to satisfy covered entity's obligations to provide an accounting of disclosures under 45 CFR 164.528;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for an accounting of disclosures that the business associate receives directly from the individual - such as whether and in what time and manner the business associate is to provide the accounting of disclosures to the individual or whether the business associate will forward the request to the covered entity- and the timeframe for the business associate to provide information to the covered entity.]

(k) To the extent the business associate is to carry out one or more of covered entity's obligation(s) under the HIPPA Privacy Rule, Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and

(l) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

#### Permitted Uses and Disclosures by Business Associate

(a) Business associate may only use or disclose protected health information for the purposes of:

[Option 1 – Provide a specific list of permissible purposes.]

[Option 2 – Reference an underlying service agreement, such as "as necessary to perform the services set forth in Service Agreement."]

[In addition to other permissible purposes, the parties should specify whether the business associate is authorized to use protected health information to de-identify the information in accordance with 45 CFR 164.514(a)-(c). The parties also may wish to specify the manner in which the business associate will de-identify the information and the permitted uses.]

- (b) Business associate may use or disclose protected health information as required by law.
- (c) Business associate agrees to make uses and disclosures and requests for protected health information consistent with covered entity's minimum necessary policies and procedures.
- (d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity.
- (e) Except as otherwise limited by this agreement, business associate may use protected health information for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.
- (f) Except as otherwise limited by this agreement, business associate may disclose protected health information for the proper management and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law.
- (g) [Optional] Business associate may provide data aggregation services relating to the health care operations of the covered entity.

# **Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**

(a) Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity, to the extent that such limitation may affect business associate's use or disclosure of protected health information.

- (b) Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate's use or disclosure of protected health information.
- (c) Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by, to the extent that such restriction may affect business associate's use or disclosure of protected health information.

#### **Term and Termination**

- (a) <u>Term</u>. The Term of this Agreement shall be effective as of [Insert effective date], and shall terminate on [Insert termination date or event] or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.
- (b) <u>Termination for Cause</u>. Business associate authorizes termination of this Agreement by covered entity if covered entity determines business associate has violated a material term of the Agreement.
- (c) Obligations of Business Associate Upon Termination. Upon termination of this Agreement for any reason, business associate shall return to covered entity [or, if agreed to by covered entity, destroy and provide proof of destruction] all protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, that the business associate still maintains in any form. Business associate shall retain no copies of the protected health information electronic or otherwise. This provision shall apply to protected health information in possession of business associate's subcontractors or agents. In the event that the business associate determines that returning [or destroying] the protected health information is infeasible, the business associate shall notify covered entity of the conditions that make return [or destruction] infeasible and shall continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 for as long as business associate retains the protected health information
- (d) <u>Survival</u>. The obligations of business associate under this Section shall survive the termination of this Agreement.

#### Miscellaneous

- (a) <u>Regulatory References</u>. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- (b) <u>Interpretation</u>. Any ambiguity in this Agreement shall be interpreted to permit the covered entity to comply with the HIPAA Rules.

(c) <u>Indemnification.</u> Business associate shall indemnify and hold covered entity harmless for any and all costs, including cost of defense, or other liability resulting from business associate's failure to full its obligations under this Agreement or from business associate's negligent act or omission in providing its services in compliance with the HIPAA Rules.

WHEREFORE, the	e parties have executed this agreement on _	, 20
		_ ("Covered Entity")
	Signature:	
	Title: Printed Name:	
		_ ("Business Associate")
	Signature:	
	Title:	
	Printed Name:	