I. Policy

The HIPAA Privacy Rule and HITECH regulations permits a covered entity to disclose protected health information to a business associate, and may allow the business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A person or entity qualifies as a “business associate” if the person or entity performs or assists in performing, for or on behalf of the covered entity, business support functions/services that involve the use of protected health information. UW-Madison follows the HIPAA Privacy Rule when disclosing protected health information to external parties acting as business associates. This document prescribes procedures for handling such arrangements with external parties who are UW-Madison’s business associates, as defined in the Privacy Rule.

II. Definitions

A. Business Associate: A person or entity not affiliated with UW-Madison that performs or assists in performing, for or on behalf of any unit in the UW-Madison Health Care Component, business support functions/services that involve the use of Protected Health Information. (A list of possible Business Associates is attached hereto as Exhibit A.)

NOTE: A health care provider that assists in providing treatment to patients is not considered to be a Business Associate.

B. Business Associate Agreement: A contract entered into between UW-Madison and an external party that contains specific terms and conditions, as required by the HIPAA Privacy Rule, governing the use and disclosure of protected health information by business associates. For purposes of this policy, a Business Associate Agreement refers to both a stand-alone contract with the required HIPAA language or a broader contract that incorporates the required HIPAA language with other provisions.

C. HITECH: The Heath Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment
Act of 2009, to promote the adoption and meaningful use of health information technology.

D. UW-Madison Health Care Component (“UW HCC”): Those units of the UW-Madison that have been designated by the University as part of its health care component under HIPAA. For a complete list of the campus units that comprise the Health Care Component, refer to UW-Madison Privacy Policy # 1.1 “Designation of the UW-Madison Health Care Component”.

E. Unit: A unit of the UW-Madison campus that has been designated as part of the UW-Madison Health Care Component.

F. Protected Health Information (“PHI”): Health information or health care payment information, including demographic information, that identifies the individual or can be used to identify the individual. PHI does not include student records or employment records. PHI may take any form, including written, oral, and electronic form.

G. UW-Madison Privacy Coordinator: Those individuals within each unit delegated to, in collaboration with the UW-Madison Privacy Officer, ensure their unit’s compliance with the HIPAA Privacy Rule regulations and UW-Madison’s policies implementing those regulations.

H. UW-Madison Privacy Officer: The individual appointed by UW to be the Privacy Officer under 45 C.F.R. § 164.530(a)(1)(i) of the HIPAA Privacy Rule.

III. Procedures

A. Business Associate Agreements Required. Each unit must ensure that its Business Associates execute a Business Associate Agreement, in the form prescribed below.

B. Signatory Authority For Business Associate Agreements.
University of Wisconsin-Madison  
Policy and Procedure

Policy Number:  6.1  
Policy Title: Managing Arrangements with Business Associates of the  
University of Wisconsin-Madison  
Effective Date:  March 12, 2003  
Last Revision Date:  July 20, 2014  
Page 3 of 8

1. UW-Madison Purchasing Services. The Director of Purchasing Services shall execute all Business Associate Agreements on behalf of UW-Madison, except as set forth in subsections (2) and (3), below.

2. Delegated Agents. Some individuals within certain units have been granted signatory authority by Purchasing Services with respect to purchases or agreements up to a certain dollar amount. These Delegated Agents have authority to execute Business Associate Agreements in connection with any agreements within the scope of their signatory authority. A unit with a Delegated Agent may wish to appoint its Delegated Agent to be its unit Privacy Coordinator.

3. Others with Signatory Authority. If necessary, any UW-Madison employee other than those listed above who has authority to sign contracts on behalf of UW-Madison may execute a Business Associate Agreement.

D. Process for Negotiating and Executing Business Associate Agreements.

1. Unit-Specific Arrangements. Each unit shall be responsible for identifying all unit-specific arrangements that require a Business Associate Agreement.

   a. The unit shall negotiate the Business Associate Agreement with the vendor or other party and shall be responsible for obtaining a signed copy of the Agreement from the vendor. (See Section E, below, regarding the proper form of the Agreement). If questions or problems arise during the negotiation process, units should contact the Director of Purchasing Services, who shall consult as necessary with the UW-Madison Privacy Officer and/or UW-Madison Office of Legal Affairs.

   b. Once the signed Agreement has been obtained, it must be forwarded to the Director of Purchasing Services (or the
unit’s Delegated Agent, if applicable), for counter-signature, along with a completed Contract Approval Cover Sheet (such forms are available through Purchasing Services). If the Agreement is in connection with a new arrangement that involves payment by UW-Madison for purchased services, a requisition order must also be forwarded with the Agreement.

c. Once received from the unit, Purchasing Services (or the Delegated Agent) will review the Agreement, counter-sign it, and send a fully executed copy of the Agreement to the vendor or other party. A copy of the Agreement will also be sent to the UW-Madison Privacy Officer and to the unit Privacy Coordinator.

2. Multiple unit or Institution-Wide Arrangements.

a. Purchase Arrangements. Purchasing Services shall be responsible for identifying all existing and new institution-wide and multi-unit purchase arrangements that require a Business Associate Agreement. Purchasing Services shall work with affected units to implement such Business Associate Agreements.

b. Non-Purchase Arrangements. The UW-Madison Privacy Officer shall be responsible for identifying all institution-wide and multi-unit arrangements not involving payment for services that require a Business Associate Agreement and for ensuring the execution of such Business Associate Agreements.

3. Maintaining Business Associate Agreements.

a. When Purchasing Services or a Delegated Agent counter-signs a Business Associate Agreement, they shall retain a copy thereof and forward the original to the UW-Madison Privacy Officer.
b. Units should maintain copies of all Business Associate Agreements to which they are a party.

c. The original of each Agreement shall be maintained by the Privacy Officer for a period of six years from the time the Agreement expires or is terminated.

E. Form of Business Associate Agreement. A template Business Associate Agreement is available on the hipaa.wisc.edu website under the Forms tab. If the Business Associate seeks to negotiate alternative language or presents its own version of a Business Associate Agreement, that alternative language must be approved by the Director of Purchasing Services, who shall consult as necessary with the UW-Madison Privacy Officer and/or UW-Madison Office of Legal Affairs.

F. Disclosures Prohibited. As of April 14, 2003, no unit, or any employee thereof, may disclose any PHI to a Business Associate unless a Business Associate Agreement has been executed.

G. Violations of the Business Associate Agreements.

1. Any employee of a unit who becomes aware of a pattern of activity or practice on the part of a Business Associate that violates the Business Associate Agreement shall report the violation as soon as possible to the unit Privacy Coordinator.

2. When a violation is reported, the unit Privacy Coordinator shall report the violation as soon as possible to the UW-Madison HIPAA Privacy Officer.

3. The HIPAA Privacy Officer and unit Privacy Coordinator shall determine whether the violation is a “material breach” of the Business Associate Agreement.

4. If the violation is determined to be a “material breach,” the Privacy Officer and unit Privacy Coordinator shall decide on an
appropriate course of action consistent with the Privacy Rule and the terms of the Business Associate Agreement. Such course of action must include reasonable steps to mitigate, to the extent possible, any harm caused by the violation and reasonable steps to end any continuing violation. If the Business Associate continues to engage in conduct in violation of the Business Associate Agreement, the unit shall terminate its relationship with the Business Associate. If termination is not possible, the UW-Madison HIPAA Privacy Officer shall report the violation to the Secretary of the Department of Health and Human Services.

H. Termination of the Business Associate arrangement. When UW-Madison’s relationship with the Business Associate terminates, for whatever reason (e.g. early termination or end of contract term), the unit must:

1. Facilitate a return of the PHI from the Business Associate;
2. Obtain a certification from the Business Associate that it has destroyed the PHI; or
3. If the parties agree that return or destruction is infeasible, obtain certification from the Business Associate that it will continue to protect the PHI as required under the Agreement for so long as the Business Associate maintains the PHI.

IV. Documentation Requirements

Purchasing Services (or a Delegated Agent, as applicable) and the HIPAA Privacy Officer shall maintain copies of all Business Associate Agreements for a period of 6 years from the date the Agreement expires or is terminated. Additionally, any certifications obtained from the Business Associate as described above in III. H. should be maintained for so long as the Business Associate Agreement is maintained.

V. Forms
Business Associate Agreement
Certification That PHI Destroyed or Destruction Infeasible (Sample)

VI. References

- 45 C.F.R. § 160.103 (HIPAA Privacy Rule)
- 45 C.F.R. § 164.501 (HIPAA Privacy Rule)
- 45 C.F.R. § 164.502(e) (HIPAA Privacy Rule)
- 45 C.F.R. § 164.504(e) (HIPAA Privacy Rule)

VII. Related Policies

Policy Number 6.2 “Managing Incoming Business Associate Contracts”

VIII. For Further Information

For further information concerning this policy, please contact the UW-Madison HIPAA Privacy Officer or the appropriate unit HIPAA Privacy Coordinator or sub-Coordinator. Contact information is available within the “Contact Us” tab at hipaa.wisc.edu.

Reviewed By
Chancellor
Chancellor’s Task Force on HIPAA Privacy
UW-Madison HIPAA Privacy Officer
UW-Madison Office of Legal Affairs

Approved By
Interim HIPAA Privacy and Security Operations Committee
Managing Business Associate Arrangements
Exhibit A

Examples of Potential Business Associates:

- Medical device or equipment vendors
- Medical software (for records, scheduling, billing, etc.) vendors
- Medical records copying services
- Medical records storage/disposal companies
- Medical transcription services
- Medical billing services
- Accreditation organizations with access to PHI
- Consulting companies with access to PHI
- Entities performing data analysis on PHI
- Companies providing marketing services involving the use of PHI
- Collection agencies using PHI
- Other entities performing any of the following services involving the use of PHI: claims processing or administration; utilization review; quality assurance; practice management; repricing; or legal, actuarial, accounting, management, administrative, or financial services.