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Department: UW Medicine Compliance

Subject: PP-12 Use & Disclosure of Protected Health Information by Business Associates

Policy Number: 12

Effective Date: January 22, 2007

Review Date: January 22, 2007

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***Purpose:***

Business associates are contractors and businesses who are not members of the University of Washington or UW Medicine workforce and who are, or will be, performing a service or activity for on behalf of the University of Washington or UW Medicine involving the use or disclosure of individually identifiable health information<sup>1</sup>. The purpose of this policy is to describe the standards under which the business associates' assurances can be considered satisfactory.

***Policy:***

UW Medicine entities must obtain satisfactory assurances from all of their business associates. UW Medicine is required to obtain satisfactory assurance that business associates<sup>2</sup> appropriately safeguard Protected Health Information (PHI)<sup>3</sup> that may be created or received on our behalf. PHI may be disclosed to a Business Associate (BA) only to help UW Medicine carry out their health care functions – not for independent use by the BA. UW Medicine may permit a BA to create, receive, maintain, or transmit PHI on our behalf.

A UW Medicine entity that provides PHI to another health care provider for treatment, payment or health care operations of an individual does not need to execute a BA Agreement with the other health care provider.

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<sup>1</sup> "Individually identifiable health information" is health information 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. See "Definitions" section for further description of "individually identifiable health information"

<sup>2</sup> Examples of "Business Associates" include: Lawyers, auditors, consultants, 3<sup>rd</sup> party administrators, healthcare clearinghouses, data processing firms, billing firms, or other covered entities that are utilized by covered entities to perform their health care activities and functions. See "Glossary" for further description of "Business Associate".

<sup>3</sup> Protected Health Information (PHI) means health information 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 that is transmitted or maintained electronically or in any other form or medium. See "Definitions" section for further description of "Protected Health Information".

**I. SATISFACTORY ASSURANCE**

Before any disclosure of PHI is made to a BA, UW Medicine requires the BA to provide written assurances that the BA:

- will use the information only for the purposes for which the BA was engaged,
- will safeguard the PHI from misuse, and
- will help UW Medicine comply with the entities' duties to provide individuals with access to health information about them and to account for disclosures.

**II. DOCUMENTATION**

UW Medicine must document BA assurances in writing by executing an agreement with the BA. Such privacy and information security agreements are generally included in the contract between the UW Medicine entity and the BA, although where both parties are government entities, a Memorandum of Understanding can contain the privacy and information security agreement.

A) Required Elements.

Every BA Agreement must do three things:

- 1) Establish the permitted and required uses and disclosures of PHI by the BA.

A BA Agreement may not authorize the BA to use or further disclose PHI except:

- a) To permit the BA to provide data aggregation services as needed for health care operations of the UW Medicine entity;
- b) To permit the BA to use or disclose PHI if necessary for the proper management and administration of the BA or to carry out the legal responsibilities of the BA; or when the BA has (1) obtained the third person's assurances of confidentiality and no further use, and (2) the third person notifies the BA of any instances in which confidentiality is breached.

- 2) Require the BA to take and refrain from taking specific actions respecting the PHI.

The Agreement must:

- a) Prohibit any further use or disclosure of the information for any other purpose than that stated in the BA Agreement or as permitted by law;

- b) Require appropriate administrative, physical, and technical safeguards to prevent use or disclosure of the information other than as provided in the BA Agreement and to reasonably and appropriately protect the confidentiality, integrity, and availability of PHI that the BA creates, receives, maintains, or transmits on behalf of UW Medicine. (for example, by controlling physical access to a computer or using security technologies for both paper and electronic records);
- c) Require the reporting of any use or disclosure that is not provided for in the BA Agreement to UW Medicine;
- d) Require the reporting of any security incident of which it becomes aware to UW Medicine;
- e) Require assurances that, the same restrictions and conditions that apply to the BA also apply to any agent, including subcontractors, of the BA;
- f) Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect the information;
- g) Require the BA to make PHI available in accordance with HIPAA and state laws governing access of individuals to PHI. See UW Medicine Privacy Policy: *PP-23 Access of Individuals to Protected Health Information (PHI)/Designated Record Set*;
- h) Require the BA to make PHI available for amendment and to incorporate amendments in accordance with HIPAA and state law governing amendment of PHI. See UW Medicine Privacy Policy: *PP-24 Amendment of Protected Health Information (PHI)/Designated Record Set*;
- i) Require the BA to make information available to provide an accounting of disclosures in accordance with HIPAA and state law governing accounting of disclosures of PHI. See UW Medicine Privacy Policy: *PP-25 Accounting of Disclosures of Protected Health Information*;
- j) Require the BA to make available to the U. S. Department of Health and Human Services or its agents the BAs internal practices, books and records relating to the use and disclosure of PHI received from or created on behalf of a UW Medicine entity;
- k) Require that, upon termination of the Agreement:

- i. The BA return or destroy all PHI received from or created on behalf of the UW Medicine entity and the BA is prohibited from retaining any copies of the PHI; or
  - ii. Where PHI is not destructible or returnable, the BA must extend the confidentiality protections and limit further uses and disclosures to only those purposes that makes returning or destruction infeasible.
- 3) Authorize termination of the Agreement in the event of breach  
UW Medicine must be allowed to terminate the BA Agreement if the BA violates a material term of the Agreement. Where termination is not feasible, UW Medicine must report the problem to the Secretary of the U.S. Department of Health and Human Services. If it is inconsistent with the law pertaining to the obligations of UW Medicine or its BA, then the BA Agreement may omit the requirement authorizing termination in the event of a violation.

B) Additional Guidelines

- 1) Governmental entities  
When the BA is a governmental entity, UW Medicine may enter a Memorandum of Understanding to document the BA's privacy, security, and electronic exchanges assurances. The Memorandum of Understanding must contain terms that accomplish the objectives of the BA Agreement. See discussion above under Policy section (III).
- 2) Legally required performance  
If a BA is required by law to perform a function or activity on behalf of or in service to UW Medicine, then UW Medicine may disclose PHI to the BA as necessary without obtaining assurances in the form of a privacy agreement; provided, however, that UW Medicine undertakes a good faith attempt to ensure the BA implements appropriate safeguards. If the attempt to obtain written assurance fails, the UW Medicine entity must document the attempt and specify the reasons for the failure.
- 3) Compliance Issues  
When UW Medicine knows of a pattern of activity or practice that constitutes a material breach or a violation of the BA's obligation under the Agreement, UW Medicine must take reasonable steps to remedy the breach or end the violation. Where reasonable steps to remedy the breach or end the violation are unsuccessful, then UW Medicine must:
  - a) Terminate the Agreement; **or**

- b) If termination is not feasible, then report the problem to the Secretary of the U. S. Department of Health and Human Services.

**Procedures:**

**I. Initiating a New Business Associate Contract**

<b>Step</b>	<b>Action</b>
1	<p>Department managers initiating a contract evaluate the other party to the contract to determine whether all three criteria that define a Business Associate exist:</p> <p>A) The outside entity or individual is not a member of the University of Washington or UW Medicine workforce;</p> <p>B) The outside entity or individual will be or is performing a service or activity “for” or “on behalf of” the University of Washington or UW Medicine; <b>and</b></p> <p>C) The services or activities the outside entity or individual will be or is performing involve the use or disclosure of individually identifiable health information.</p>
2	<p>If the contract for services or goods meets the Business Associate contract criteria, the department manager works with the buyer from purchasing to complete the Business Associate Agreement. Then, the buyer from purchasing attaches the BA Agreement to the contract. See “UW Medicine Business Associate Agreement” (Attachment A).</p>

**II. Initiating a New Business Associate Purchase Order**

<b>Step</b>	<b>Action</b>
1	<p>Department managers initiating a purchase order evaluate the purchase of services or goods to determine if the contract meets all three criteria for the BA definition:</p> <p>A) The outside entity or individual is not a member of the University of Washington or UW Medicine workforce;</p>

	<p>B) The outside entity or individual will be or is performing a service or activity “for” or “on behalf of” the University of Washington or a UW Medicine entity; <b>and</b></p> <p>C) The services or activities the outside entity or individual will be or is performing involve the use or disclosure of individually identifiable health information.</p>
<p>2</p>	<p>If the purchase order for services or goods meets the Business Associate contract criteria, the department manager works with the buyer from purchasing to incorporate the following Business Associate Agreement on the purchase order:</p> <p>“NOTE: The attached 3 page "BUSINESS ASSOCIATE ADDENDUM “is a part of this purchase order. The UW wishes to conduct transactions involving the disclosure of information to the Business Associate for the purpose of conducting the activities set forth herein. The information may be used for the following purposes:</p> <ol style="list-style-type: none"> <li>1. _____</li> <li>2. _____</li> <li>3. _____</li> <li>4. _____</li> </ol> <p>The department manager and the buyer from purchasing will complete the Business Associate Addendum and the buyer from purchasing attaches the Addendum to the purchase order. See “UW Medicine Business Associate Agreement” (Attachment A).</p>

**III. Initiating a Memorandum of Understanding**

Step	Action
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1	<p>Department managers initiating a contract or purchase order evaluate the contract or purchase order to determine whether all three criteria that define a Business Associate exist:</p> <p style="padding-left: 40px;">A) The outside entity or individual is not a member of the University of Washington or UW Medicine workforce;</p> <p style="padding-left: 40px;">B) The outside entity or individual will be or is performing a service or activity “for” or “on behalf of” the University of Washington or a UW Medicine entity; <b>and</b></p> <p style="padding-left: 40px;">C) The services or activities the outside entity or individual will be or is performing involve the use or disclosure of individually identifiable health information.</p>
2	<p>If the UW Medicine entity and its BA are both considered governmental entities, then a Memorandum of Understanding should be executed. The department manager works with the Privacy Official and the buyer from purchasing to complete a Business Associate Memorandum of Understanding and the buyer from purchasing attaches the memorandum to the contract/purchase order.</p>

**IV. Terminating a Business Associate Agreement**

A) Suspected or Known Violations:

Step	Action
1	If a violation(s) of the Business Associate Agreement is suspected or discovered, the department manager is required to alert the entity’s Privacy Official of the violation(s) and request investigation.
2	If the suspected violation is substantiated, the department manager works with purchasing to find an alternative Business Associate to provide the goods or services and with purchasing and legal counsel to terminate the existing contract.

B) Reporting to the Secretary of U.S. Department of Health & Human Services Where Termination is Not Feasible

Step	Action
1	When a Business Associate has violated its contract and alternatives cannot be found to provide the goods or services supplied under the contract, the department manager must report the violation(s) to the entity’s Privacy Official, and advise the Privacy Official those alternative goods or services cannot be found. The department manager shall also request the Business Associate to act to correct

	the violation and to prevent future violations.
2	The entity's Privacy Official will work with the UW Medicine Privacy Officer and legal counsel to report the violation, detail efforts to locate alternatives and measures taken to correct the violation, and to request that the UW Medicine entity be permitted to continue its relationship with the current Business Associate.

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**References:**

- I. 45 CFR Part 160 and 164; Sections 160.103 – Definitions; 164.502 – “Uses and disclosures of protected health information: general rules”, paragraph (e) disclosures to business associates; 164.504 – “Uses and disclosures: organizational requirements”, paragraph (e) – business associate contracts.
- II. 45 CFR Part 164; Section 164.308(a)(8) (b) (1) Business Associate Contracts and other Arrangements
- III. 45 CFR Part 164; Section 164.308(a)(8) (b) (4) Written Contract or Other Arrangements
- IV. 45 CFR Part 164; Section 164.314 (a) Business Associate Contracts or other Arrangements

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UW Privacy Officer: \_\_\_\_\_ Date: \_\_\_\_\_  
John A Coulter, Associate Vice President for Medical Affairs

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