

 <small>*Excludes Rex Healthcare</small>	Name of Policy	BUSINESS ASSOCIATES
	Policy Number	B-2
	Date This Version of Policy Effective	February 2006
	Department Responsible for Review	UNC HCS HIPAA Policy Committee

POLICY:

In accordance with the Health Insurance Portability and Accountability Act of 1996 and its accompanying regulations (HIPAA), the UNC Health Care System (UNC HCS) must establish agreements and procedures with certain persons or entities which provide services to or on behalf of UNC HCS (Business Associates, as defined below) to ensure compliance with HIPAA regulations related to Business Associates.

DEFINITIONS:

Business Associate: A business associate is a person or entity which provides certain functions, activities, or services for or to UNC HCS involving the use and/or disclosure of protected health information (PHI), and such person or entity is not a component of UNC HCS or its workforce.

Contract: A contract with a business associate can include any of the following: a purchase order, signed and executed Request for Proposal (RFP), a signed written document, or any entity-approved purchasing mechanism. If an arrangement with a vendor is only an oral arrangement, the arrangement must be documented and signed by an authorized representative.

Entity: Those entities which comprise the University of North Carolina Health Care System, including UNC Hospitals, UNC Physicians & Associates, Rex Healthcare (through adoption of this policy at Rex Healthcare), and the clinical activities of the UNC-CH School of Medicine.

PROCEDURE:

I. **Identify Business Associates:**

The identification of Business Associates is the responsibility of the department receiving the services from the Business Associate by indication on the requisition form/contract cover, routing sheet or any entity-approved purchasing mechanism of the following departments (collectively, the "Purchasing Departments"):

- a. UNC Hospitals Purchasing and Legal Departments;
- b. Rex Hospitals Purchasing and Compliance Departments;
- c. the UNC School of Medicine departments in conjunction with the Privacy Officer of the School of Medicine and Office of University Counsel; and
- d. UNC CH Materials and Disbursements Services.

The Purchasing Departments and the applicable entity's Legal Offices and Privacy/Security Officers can serve as resources to assist the departments in identifying Business Associates.

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- II. Document Business Associates: Each entity's Purchasing Department or its designee will maintain a database of its Business Associates.
- III. Business Associate Agreements: The UNC HCS HIPAA Privacy Committee has adopted a form Business Associate Agreement in accordance with HIPAA guidelines, and that Committee will be responsible for amending and/or updating the form Business Associate Agreement, as required.
- IV. Negotiation of Business Associate Agreements: Each Purchasing Department or its designee will be responsible for negotiating its Business Associate Agreements with each designated Business Associate of one of the departments which it serves, using the form Business Associate Agreement. In the event a Business Associate desires to make a minor modification of the terms of the Business Associate Agreement which would not affect HIPAA compliance, the Purchasing Department has the authority to negotiate with the Business Associate, using discretion in making any such modifications. In the event the requested modification is not minor in nature and/or would affect HIPAA compliance, the request will be brought to the applicable entity's legal department for review and determination.
- V. Execution and Maintenance of Business Associate Agreements: The Purchasing Departments or their designees will ensure execution of Business Associate Agreements with designated Business Associates and will maintain originals of such Agreements. Each Purchasing Department or its designee will institute a tracking system which will document the execution of a Business Associate Agreement with each designated Business Associate of one of the departments which it serves. In the event a Business Associate Agreement cannot be obtained, such failure shall be brought to the Business Associate Subcommittee by the applicable Purchasing Department. If the underlying arrangement with the designated Business Associate would not allow for an extension under HIPAA for obtaining such agreement prior to April 14, 2004, or if a Business Associate Agreement cannot be obtained under any circumstances, then the applicable Purchasing Department or its designee will coordinate with the department utilizing the services of the Business Associate, and will initiate termination of the relationship with such designated Business Associate. The termination will be communicated by the Purchasing Department or its designee to other departments affected by the termination.
- VI. Relationship Management with Business Associates: The Purchasing Departments or their designees will be responsible for managing HIPAA-related issues with Business Associates. These issues include the following:
 - a. The Purchasing Departments or their designees will determine which Business Associates require training in privacy/confidentiality/security issues pursuant to the guidelines listed in section VII below. This training will be accomplished through seminars and/or by written training materials developed by the UNC HCS HIPAA Education Subcommittee. Each Business Associate participating in training will acknowledge that it has received such training. Some categories of Business Associates require additional follow-up with respect to certain HIPAA requirements, as listed in Section VIII below. The department receiving services from Business Associates in the categories listed in Section VIII below is

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- responsible for ensuring that those Business Associates have or will receive the applicable training.
- b. The department receiving services from a Business Associate is responsible for determining which employees or agents of a Business Associate are required to sign the UNC HCS Confidentiality Statement (either by virtue of the services being provided or by contract provisions). The department receiving services from the Business Associate will be responsible for obtaining signatures on the Confidentiality Statement and for maintaining such documentation.
 - c. In the event the Purchasing Departments (or their designees) or any other department determines that a Business Associate has either breached the terms of its Business Associate Agreement or caused UNC HCS to breach the requirements of HIPAA, the issue will be referred to the applicable entity's Privacy and/or Security Officers for action. In the event the applicable entity's Privacy and/or Security Officers determine that action is required, the action will be coordinated with the applicable Purchasing Department or its designee and the department utilizing the services of the Business Associate, and will be reported to any other applicable UNC HCS committees. Such actions may include: mitigation by the Business Associate and/or termination of the relationship with the Business Associate. In the event of termination of the relationship, the termination will be communicated by the Purchasing Department or its designee to other departments affected by the termination.
- VII. Training Requirements for Business Associates: The department receiving the service from each Business Associate will assist its Business Associates in receiving the type of training discussed below, including new personnel of the Business Associate.
- a. For Business Associates which provide personnel on site who have access to PHI, regardless of medium of access: These Business Associates will receive the full training module (whether electronic or paper, as appropriate) required of employees of UNC HCS, and UNC HCS will require the Business Associate to certify that their personnel who come on site have completed the training.
 - b. For Business Associates which are not based on site, but have personnel who have continuous, unmonitored access to PHI, regardless of medium of access: These Business Associates will receive the full training module (whether electronic or paper, as appropriate) required of employees of UNC HCS, and UNC HCS will require the Business Associate to certify that their personnel who access PHI have completed the training.
 - c. For Business Associates which are on site, but have personnel who have selective, monitored access to PHI, regardless of medium of access: These Business Associates will receive a copy of the UNC HCS training materials and will be required to (i) certify that all of its personnel have obtained general HIPAA training; and (ii) compare the UNC HCS policies and procedures outlined in the training materials to the general HIPAA training provided by the Business Associate to its personnel, and, if there are material differences, train all of its personnel who service the UNC HCS account on those different policies/procedures.
 - d. For Business Associates which are not on site, but have personnel who have selective, monitored access to PHI, regardless of medium of

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access: These Business Associates will receive a copy of the UNC HCS training materials and will be required to (i) certify that all of its personnel have obtained general HIPAA training; and (ii) compare the UNC HCS policies and procedures outlined in the training materials to the general HIPAA training provided by the Business Associate to its personnel, and, if there are material differences, train all of its personnel who service the UNC HCS account on those different policies/procedures.

VIII. Follow-up Requirements: Due to the specific nature of and extent of exposure to the PHI of UNC HCS granted, Business Associates which fall within the categories listed below require additional follow-up to ensure compliance in the designated HIPAA requirements.

a. Full Clinical and Operational Training

1. Research and Quality Assurance Surveyors (interviewers for research participants, patient satisfaction, quality assurance)
2. Computer Support and Maintenance (software, hardware, network support)
3. Medical Equipment Suppliers which require patient-specific PHI (prosthetics, orthotics, hearing aids, implants, etc.) and other vendors of pharmaceuticals and therapeutic services which interact with patients on behalf of UNCHCS
4. Dictation/Transcription Services
5. Management Services (e.g., iLiant, Gentiva)
6. Waste Disposal Services (e.g., Shred-it, Bio-hazard waste disposal)
7. Data Clearinghouses for aggregating and benchmarking data (Solucient, UHC, Oryx)
8. Student Affiliations
9. Copy service
10. Outside contracted medical or operational services involving PHI
11. Coding/medical record documentation consultants
12. Temporary staffing agencies
13. Newborn photographer

b. Training and Establishing Procedures for Accounting of Disclosures

1. Management Services (e.g., iLiant, Gentiva)
2. Data Clearinghouses for aggregating and benchmarking data (Solucient, UHC, Oryx)
3. Student Affiliations
4. Acute Care facilities providing care to Hospice patients
5. Labs providing services on our behalf
6. Copy service
7. Outside contracted medical or operational services involving PHI
8. Temporary staffing agencies
9. Newborn photographer

IX. Ongoing Compliance Reviews: In order to ensure the compliance of all departments with the terms of this policy, the Purchasing Departments (or their designees) will conduct periodic compliance reviews of the UNC HCS Business Associates. Compliance reviews will include verification that all vendors which

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would meet the definition of a “Business Associate” have obtained and signed a Business Associate Agreement and Confidentiality Statements, as applicable; that all Business Associates have obtained and certified appropriate training; and that there are no outstanding issues regarding compliance by the Business Associate with the terms of the Business Associate Agreement.

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Exhibit A

Training Examples

Business Associates which provide personnel on site who have access to PHI, regardless of medium of access

- Onsite Copy Service (i.e., Smart Copy)
- Onsite Transcriptionists
- Onsite Consultants

Business Associates which are not based on site, but have personnel who have continuous, unmonitored access to PHI, regardless of medium of access

- Edix
- Billing and Collection Agencies (PerSe)
- Off Site Management Agencies (i.e., Gentiva)

Business Associates which are on site, but have personnel who have selective, monitored access to PHI, regardless of medium of access

- Newborn Photographer
- Financial Consultants
- Attorney General's Office

Business Associates which are not on site, but have personnel who have selective, monitored access to PHI, regardless of medium of access

- Outside Counsel
- Insurance Companies
- Software Vendors