
Title:	DPH Privacy and Security Manual
Chapter:	II. Administrative Policies, Business Associates
Current Effective Date:	January 30, 2004
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Purpose

The purpose of the Division of Public Health (DPH) business associates policy is to ensure that all individuals or organizations that perform specific functions, activities, or services for DHHS agencies involving the sharing of individually identifiable health information (IIHI) are appropriately identified according to the HIPAA Privacy Rule as a “business associate”; and to further ensure that “agreements” are developed to support such contractual relationships, as appropriate. This policy is in compliance with the [DHHS Policy and Procedure Manual, Section VIII, Security and Privacy](#), that establishes the NC Department of Health and Human Services (DHHS) requirements for privacy complaints.

Policy Scope:

- *HIPAA covered health care components*
- *Internal business associates*

Background

DHHS workgroups that must comply with the HIPAA Privacy Rule are referred to as ‘covered health care components’. The HIPAA Privacy Rule requires covered health care components to identify persons or entities that provide specific functions, activities, or services that involve the use, creation, or disclosure of IIHI for, or on their behalf. Such entities are referred to as business associates.

Because this department has been determined to be a hybrid entity, each DHHS division and office is required to identify components that are covered by this HIPAA requirement. Although some components were determined not to be covered health care components under HIPAA, they do perform functions, activities, or services that involve the sharing of IIHI for, or on behalf of, covered health care components thus creating business associate relationships within this department. Such persons or entities *within* DHHS are health care components that are referred to as ‘**internal business associates**’.

Components in other North Carolina state government departments/agencies or external contractors *outside* of DHHS that perform functions, activities, or services for, or on behalf of, a DHHS covered health care component, and involve the use, creation, or disclosure of IIHI are referred to as ‘**external business associates**’.

Functions, activities, and services performed by business associates that involve the use, creation, or disclosure of IIHI may include claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and re-pricing.

Policy

Business Associates

Covered health care components within the Division are required to identify their ***internal*** business associates by recognizing all of the other divisions/offices and workgroups within the Division that perform specific functions, activities, or services for, or on behalf of, the covered component when such functions or activities involve the sharing of IIHI.

The Division's covered health care components will also identify their internal business associates by recognizing any other health care component(s) or internal business associate within DHHS, that perform such functions, activities, or services for, or on behalf of DPH that involves the sharing of IIHI.

The Division's covered health care components must identify their ***external*** business associates by recognizing other State government departments/agencies and external contractors (public and private) that perform specific functions, activities, or services for, or on behalf of DPH, when such functions, activities, or services involve the sharing of IIHI.

Note: Incidental access to IIHI, while performing duties that do not typically involve the use or disclosure of such information, generally does not constitute a business associate relationship.

Business Associate Agreements

The Division must initiate agreements with their external business associates in order to share IIHI while performing specific functions, activities, or services for, or on behalf of, Division covered health care components or internal business associates.

The Division is responsible for executing agreements with external business associates that provide satisfactory assurance that the business associate will appropriately safeguard IIHI. The [Business Associate Agreement Addendum template](#) and the [Business Associate Memorandum of Understanding Addendum template](#), developed by the North Carolina Office of the Attorney General (AG), are required when contracts are initiated by the Division. Such addenda must be attached to either the Department's standard contract or the Department's standard Memorandum of Understanding (MOU) as specified in the DHHS Purchasing and Contracts Manual.

Whenever another department/agency in state government has been identified as an external business associate of the Division of Public Health, and there is no agreement in place between the two organizations, a [Business Associate Memorandum of Understanding](#) that stands alone must be developed using the template developed by the AG's Office.

Certain external contractors may be considered part of DPH's *workforce*, and therefore will not require a business associate agreement if the following criteria apply:

- The work location and/or activities of the person under contract is on the covered health care component's premises
- The person performs a substantial proportion of his/her activities at this location or under direct supervision of Division staff.

Any contractor, volunteer, intern, or non-employee who is considered part of the DPH's workforce must comply with DPH's Privacy policies and procedures.

Written agreements are not required between DHHS Divisions and Offices since the DHHS Privacy Policy Manual applies generally to the entire Department and specifically to covered components and internal business associates. However, many Memoranda of Understanding exist between Divisions and the Business Associate Agreement Addenda can be incorporated into these MOUs.

Disclosure of IHI from one health care provider to another for treatment, consultation, or referral does not require a business associate agreement. A business associate agreement is also not required when IHI is disclosed to a health plan for payment purposes. Also, business associate agreements are not required between DPH and its provider partners to exchange IHI for program reporting and program oversight, quality assurance, and monitoring. Exchanging IHI for public health purposes, public health activities, and for public health reporting required by law does not require business associate agreements.

The Division is required to take reasonable steps to correct any known material breach or violation of any business associate agreement. If such steps are unsuccessful, the agreement must be terminated, if feasible; and if not, the problem must be reported to the DHHS Privacy Officer who will determine if further actions are warranted, which could include reporting the problem and correction attempts to the United States DHHS.

Should the Division become a business associate of an agency or organization external to DHHS, the agreement initiated by the external agency or organization must be reviewed by the DPH Privacy Office and approved by the AG's Office before the Division signs it.

Implementation

Applicability of Business Associates within DPH

The following DPH workgroups have been designated as Covered Health Care Components.

- State Laboratory of Public Health
- Children's Developmental Services Agencies (state operated).

The CDSAs have been exempted from the requirements of the HIPAA Privacy Regulation, since they are covered by the Family Education Privacy Rights Act (FERPA). State-operated CDSAs do not need to comply with this policy.

The State Laboratory for Public Health (SLPH), as a covered health care component, must comply with this policy. However, in most cases the SLPH does not provide covered functions on behalf of other covered entities. The laboratory services are treatment-related and therefore do not require business associate agreements. Further, the SLPH reports test results to other DPH workgroups and entities for "required by law reporting", public health purposes (disease prevention and control) or DPH program follow-up, such as sickle cell, which is treatment-related). "Required by law reporting", public health reporting, and DPH program follow-up, do not require business associate agreements.

The HSIS Business Liaison has also been identified as a business associate of the local health departments, for whom it performs Medicaid billing services.

The DPH Internal Business Associates and other DPH workgroups that have defined business associate relationships, and the applicability of this policy are defined in the [DPH Internal Business Associate Summary Review](#). These internal business associates must comply with this policy as appropriate. As internal business associates, these DPH workgroups must comply with the DHHS and DPH privacy policies.

Handling Requests from Other Entities

All requests regarding business associates relationships from outside entities must be forwarded to the DPH Privacy Office for review. The DPH Privacy Office will review the request, consult with the Division workgroup to review the relationship with the requestor, and consult with the DHHS HIPAA Office and/or Attorney General's Office as required to clarify the request and Division response. The DPH Privacy Office will prepare the appropriate response to the request and present to DPH management for signature and distribution.

Identifying Internal and External Business Associates

The Division, because it has a covered health care component and internal business associates must evaluate specific functions, activities, and services that are provided for, or on behalf of, that component/business associate to identify all internal and external business associates as follows:

- Within the same DHHS division/office
- Within other divisions in DHHS
- Within other departments/agencies in NC State government
- Outside state government (external contractors).

The Department has developed the [HIPAA Guidance to Identifying Business Associates](#) document and [Business Associate Questionnaire](#) worksheets for classifying business associates for DHHS agencies to use in making such determinations. The DPH Privacy Office uses this guidance and the questionnaire to identify all of its business associate relationships. The Division Privacy Office works with all affected DPH covered workgroups to review internal and external organizations that perform specific functions on their behalf and that might define a business associate relationship. In addition to these tools, each agency should use two documents developed by the HIPAA Office when assessing individuals or organizations that are performing a service or activity for or on behalf of a covered health care component. The [Internal Business Associate Assessment for NC DHHS](#) was developed to assist agencies in identifying other programs within the same division and other divisions within NC DHHS that meet the definition of an 'internal business associate'. The [External Business Associate Assessment for NC DHHS](#) was developed to assist agencies in identifying divisions or programs within other NC state departments or public/private contractors that meet the definition on an 'external business associate'.

The DPH Privacy Office also reviews DPH contracts and MOUs and with the appropriate covered components and with DPH contracts management for specific services that might constitute a business associate relationship. These relationships are reviewed at the time the covered component initially creates a contract with the external contractor or develops an MOU with another department. Whenever a contract or MOU is renewed that has a Business Associate Addendum, the Business Associate Agreement is also reviewed. The DPH Privacy Office also works with DPH contracts management to ensure that all contract information for all identified business associate relationships to standard contracts are into the DHHS purchase and contracts database that monitors contract costs.

Contractual Documentation Requirements

There are no contractual documentation requirements for services provided by internal business associates, other than the agency's general documentation requirements. Documentation of services provided by other NC State government departments/agencies is accomplished through a Memorandum of Understanding. Documentation of services provided by external contractors is accomplished through a DHHS standard contract. Documentation of business associate requirements is accomplished in an addendum to the MOU or contract. Business Associate agreements must be maintained for at least six years from the date of creation. The [Business Associate Addendum For Contract template](#), the [Business Associate Memorandum of Understanding Addendum](#) and the stand-alone [Business Associate Memorandum of Understanding](#) templates have been developed by the N.C. Attorney General's Office and must be used when service providers outside of DHHS are identified as business associates. These documents include all of the HIPAA requirements to which their contractors must agree before covered health care components are allowed to share individually identifiable health information.

Beginning October 15, 2002, all new or amended DHHS contracts or MOUs were evaluated to determine whether a business associate relationship exists. If a business associate relationship does exist, the business associate agreement developed by the N.C. Office of the Attorney General must be attached to the new or amended DHHS contract or MOU before April 14, 2003. All contracts and MOUs that are initiated or amended during fiscal year 2003-2004 must have the business associate agreements attached if contractors are also business associates. By April 14, 2004, all existing contracts and MOUs that also exhibit a business associate relationship must be amended to include a business associate agreement (even if the contract period goes beyond April 14, 2004). By April 14, 2004, all known DPH business associate agreements are required to be in place.

Termination of Business Associate Relationship

Should a DHHS covered health care component or internal business associate become aware of a pattern of activity, or practice of an internal business associate that constitutes a material breach or violation of the internal business associate's obligation with respect to privacy of IIHI in its possession, such information shall be forwarded to the DHHS Privacy Officer for resolution.

Should a DHHS covered health care component or internal business associate become aware of a pattern of activity or practice of an external business associate that constitutes a material breach or violation of the external business associate's obligations with respect to IIHI specified in a contract or other arrangement, reasonable steps should be taken to cure each breach, end the violation, and/or mitigate the consequences.

If such steps are unsuccessful, the covered health care component or internal business associate may, at its discretion:

- Terminate the contract or arrangement, if feasible

- If termination is not feasible, the Agency Privacy Official/designee is responsible for reporting the breach to the DHHS Privacy Officer. The DHHS Privacy Officer is responsible for resolution, which may include reporting the problem to the US DHHS Secretary at:

Office for Civil Rights
U.S. Department of Health & Human Services
Atlanta Federal Center, Suite 3B70
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8909
Phone: (404) 562-7886
Fax: (404) 562-7881

Tracking of Business Associates

Each agency is required to track their internal business associates by maintaining current documentation of their internal business associates throughout the year on the [Business Associate Questionnaire](#) worksheets. At the end of the state fiscal year, each covered component is required to send a copy of the “Division Business Associates” and “DHHS Business Associates” worksheets from the [Business Associate Questionnaire](#) to the DHHS Privacy Officer.

DHHS agencies shall track their external business associates through the contracts that are entered into the Department database for purchasing and contracts by checking the business associate field as appropriate.

Training

DHHS covered health care components and internal business associates are not required to provide privacy training to their external business associates; nor are they required to monitor the privacy protections for IIIHI that are instituted by their external business associates.

For Relevant Forms:

- [Business Associate Addendum For Contract template](#)
- [Business Associate Addendum For Memorandum of Understanding template](#)
- [Business Associate Memorandum of Understanding – Stand Alone template](#)
- [DHHS HIPAA Guidance for Identifying Business Associates](#)
- [Business Associate Questionnaire](#)
- [DPH Internal BA Review Summary](#)
- [DPH Internal BA Identification](#)
- [DPH DHHS Bas](#)
- [DPH State Lab DHHS BAs](#)
- [DPH Inventory of External BAs and Trading Partners](#)

References: DHHS Directive Number III-11; DHHS Policy and Procedure Manual, Section VIII, Security and Privacy, DPH HIPAA Compliance Statement, 45 CFR 160.103, 164.502(e), 164.504(e), 164.514(e)

For questions or clarification on any of the information contained in this policy, please contact the DPH Privacy Office at HIPAA.DPH@ncmail.net.