



**North Carolina Department of
Health and Human Services**

HIPAA
Guidance for Identifying Business Associates
Final Version

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Acronyms and Abbreviations

DHHS	North Carolina Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
MOU	Memorandum of Understanding
PHI	Protected health information
PMO	DHHS HIPAA Program Management Office
SOE	State-owned and DHHS-operated entities

Definitions

Business Associate = A business associate relationship may arise when a person or organization performs a function or activity on behalf of a covered entity or provides certain legal, financial or management services to the covered entity and the function, activity or services involved in the use or disclosure of individually identifiable health information. Examples of Business Associate functions are: activities by a Trading Partner, claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management, practice management, and re-pricing; legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services.

Covered Entity = A health plan; a health care clearinghouse; or a health care provider who transmits any health information in electronic form in connection with an electronic transaction.

Covered Functions = Those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Covered Health Care Component =

- (1) Components of a covered entity that perform covered functions are part of the health care component.
- (2) Another component of the covered entity is part of the entity's health care component to the extent that:
 - (i) It performs, with respect to a component that performs covered functions, activities that would make such other component a business associate of the component that performs covered functions if the two components were separate legal entities; and
 - (ii) The activities involve the use or disclosure of protected health information that such other component creates or receives from or on behalf of the component that performs covered functions

Health Care Provider = A provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes bills or is paid for health care in the normal course of business.

Health Information = Any information, whether oral or recorded in any form or medium, that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Hybrid Entity = A single legal entity that is a covered entity and whose covered functions are not its primary functions.

Individually Identifiable Health Information = Information that is a subset of health information, including demographic information collected from an individual, and:

- (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
 - (i) That identifies the individual; or
 - (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Oversight Agency = *Oversight agencies* are agencies that are responsible for monitoring government programs and the health care system. These oversight agencies are not performing services for or on behalf of the covered entities and so are not business associates of the covered entities. For example, HCFA, the federal agency that administers Medicare, is not required to enter into a business associate contract in order to disclose protected health information. Protected health information may be exchanged between covered health care components and oversight agencies without consent, authorization or Business Associate agreement.

Protected Health Information = *Protected health information* means individually identifiable health information:

- (1) Except as provided in paragraph (2) of this definition, that is:
 - (i) Transmitted by electronic media; or
 - (ii) Maintained in any medium described in the definition of *electronic media* at § 162.103 of this subchapter; or
 - (iii) Transmitted or maintained in any other form or medium.
- (2) *Protected health information* excludes individually identifiable health information in:
 - (i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and
 - (iii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv).

State-owned and DHHS-operated entity (SOE) = SOE means those health care facilities that are owned by the state under the legal authority of DHHS, including 4 psychiatric hospitals, 5 mental retardation centers, 2 alcohol and drug abuse treatment centers, NC Special Care Center, Wright School, Whitaker School, Eastern Adolescent Treatment Center, Governor Morehead School, 2 schools for the deaf, and 13 developmental evaluation centers.

Workforce = *Workforce* means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

1. Introduction

DHHS divisions and offices, with HIPAA covered health care components, are required to identify individuals or entities that:

- 1) perform or assist with a specific function or activity and/or provide certain identified services for (or on behalf of) covered health care components within their division or office; and
- 2) Exchange individually identifying health information that is protected by the HIPAA Privacy Regulations (hereinafter referred to as “protected health information”).

The provision of the above referenced services will constitute a business associate relationship that may require an agreement that includes required HIPAA language, to ensure the protection of health information.

DHHS divisions and offices currently receive services from different individuals and agencies. Some of those services are provided by workgroups in the same division or office, by workgroups in other DHHS division or offices or by workgroups in other state government departments; while other services are provided by private or public external contractors or vendors. Many of those services may translate into a business associate relationship. The initial step in identifying business associates is to categorize all service providers into the following categories:

- 1) Division Business Associate: Other workgroups within the same division or office that perform specific services and the functions or activities involve the use or disclosure of protected health information that would make the work group a division business associate of a covered health care component;
 - 2) DHHS Business Associate: Workgroups in other DHHS divisions and offices that perform specific services for a covered health care component, functions or activities, involve the use or disclosure of protected health information that would make the DHHS division or office workgroup a business associate of a covered health care component;
- 3) State Government Business Associate: Workgroups in other departments of state government that perform specific services on behalf of the DHHS covered health care component and the functions or activities involve the use or disclosure of protected health information that would make the non-DHHS department workgroup a business associate of a DHHS covered health care component;
 - 4) External Business Associate: Public/Private Contractors/Vendors that perform specific services on behalf of the DHHS covered health care component and the activities involve the use or disclosure of protected health information that would

make the contractor or vendor a business associate of a DHHS covered health care component;

Contractors that do not perform specific services that meet the requirements for a business associate relationship (i.e., no exchange of protected health information) will continue to be processed as routine contracted services, according to DHHS policy and procedure. In order to implement the Business Associate standard, each impending contracted service will have to be evaluated as to whether it will be handled as a standard contract/MOU, or whether it will be processed as a business associate agreement.

2. Business Associate Identification Objectives

The primary goals of the DHHS HIPAA Business Associate identification process is to:

- 1) Identify those persons/entities that constitute a business associate relationship so DHHS covered healthcare components will know which business associates will be considered part of their workforce or when MOUs or contracts containing specific HIPAA language will be required; and
- 2) Identify all areas within DHHS that will be impacted by HIPAA.

3. Scope of Business Associate Identification

The scope of the process to identify business associates will initially apply to DHHS covered health care components. After the identification process is complete, each Division, Office and SOE that is not a covered health care component will be provided a list of the covered health care components. The non-impacted agencies will be requested to specify any activities they may perform on behalf of the covered health care component where protected health information is received. This will serve as a crosscheck between the DHHS agencies.

4. Business Associate Identification Process

The size and complexity of DHHS has resulted in the identification of the department as a Hybrid Entity. Because DHHS has been determined to be a Hybrid Entity, only those DHHS divisions and offices that have certain programs, which meet the HIPAA definition of a covered health care component, are required to evaluate their current service providers to identify those that will require business associate relationships. The four categories of business associates are further defined to aid divisions and offices in categorizing their business associate relationships.

4.1. *Division Business Associates*

There are relationships within the same division or office that would otherwise qualify as an external business associate arrangement. However, since the covered health care component and its “business associate” fall under the same legal entity, both entities will need to comply with the HIPAA requirements. This will generally occur when organizational responsibilities require one division or office workgroup to

perform a service on behalf of a covered health care component within the same division or office and the two entities will share protected health information. The Division Business Associate may or may not be under the direct supervision of the covered health care component but, for the purposes of HIPAA, is considered a member of the covered health care component's workforce. This arrangement will not require a written contract or agreement; however, the covered health care component will need to maintain documentation verifying that each member of the workforce has been trained in and will comply with HIPAA-compliant policies and procedures.

Example: DMH/DD/SAS workgroup that supports the HEARTS system used by the state institutions - the state institutions are the covered health care components and the DMH/DD/SAS workgroup that supports HEARTS is performing services on behalf of each of the institutions.

4.1.1. Identifying Division Business Associates

Careful review of all activities and functions, that involves the exchange of protected health information, that is provided throughout the entire division or office to a covered health care component is essential in order to identify those services that would require a business associate relationship.

If a covered health care component in a division or office is receiving a service that involves the exchange of protected health information from another workgroup in the same division or office, a Division Business Associate relationship exists and both workgroups must comply with the HIPAA Privacy Regulations. Identification of division business associates also alerts the covered health care component to other workgroups that must be **excluded** from access to protected health information maintained by the covered health care component.

4.2. DHHS Business Associates

There are relationships between different divisions or offices within DHHS that would otherwise qualify as an external business associate arrangement. This will occur when one division or office performs a service on behalf of a covered health care component within another DHHS division or office, and the two workgroups share protected health information. Since the two workgroups fall under the same legal entity (i.e., DHHS), both workgroups will need to comply with the HIPAA requirements. The DHHS Business Associate, for the purposes of HIPAA, is considered a member of the covered health care component's workforce. This arrangement will not require a written contract or agreement; however, this arrangement will require a DHHS Directive that applies to all covered health care components and their business associates within the department, so that policies and procedures for handling protected health information in each affected division or office will be consistent. The covered health care component will need to maintain

documentation verifying that each member of the workforce has been trained in and will comply with HIPAA-compliant policies and procedures.

Example: In the DHHS Controller's Office, the Central Billing Office (CBO) performs a billing service on behalf of the DMH/DD/SAS state institutions and the CBO has access to PHI.

4.2.1. Identifying DHHS Business Associates

Careful review of all services provided to a covered health care component in one DHHS division or office by a workgroup from another DHHS division or office is essential in order to identify any services that would require a business associate relationship.

If a covered health care component in one DHHS division or office is receiving a service from a workgroup in another DHHS division or office, a DHHS Business Associate relationship exists and the HIPAA Privacy Regulations apply to the protected health information exchanged between the workgroups in the two divisions or offices. Identification of DHHS Business Associates also alerts the covered health care component to other workgroups that must be **excluded** from access to protected health information maintained by the covered health care component.

4.3. State Government Business Associates

There are relationships between DHHS division or offices and division or offices within other state government departments, when a workgroup in another department performs a service on behalf of a covered health care component within DHHS and they will share protected health information. The State Government Business Associate is not a member of the covered health care component's workforce; therefore, this arrangement will require a Memorandum of Understanding (MOU) between the two departments, and the MOU must contain the required HIPAA language and requirements.

Example: The Attorney General's Office, in the Department of Justice, represents DHHS divisions and offices in legal matters and oftentimes this involves the sharing of protected health information.

4.3.1. Identifying State Government Business Associates

Careful review of all activities and functions involving the exchange of protected health information, that is provided to a covered health care component in a DHHS division or office by a workgroup from another state government department, is essential in order to identify any services that would require a business associate relationship.

If a covered health care component in a DHHS division or office is receiving a service from a workgroup in another department of state government and PHI is exchanged, a State Government Business Associate relationship exists. Therefore, the HIPAA Privacy Regulations apply to the protected health information exchanged between the two entities. Identification of State Government Business Associates also alerts the covered health care component to other workgroups in other departments of state government that must be **excluded** from access to protected health information maintained by the covered health care component.

All division or office staff in the covered health care component and the state government business associates must be trained to follow the HIPAA Privacy Regulations and must enter into a Memorandum of Understanding (MOU) in order to ensure the protection of health information maintained by both entities. The DHHS Office of Purchase and Contracts is responsible for developing a standard departmental MOU that is to be used in developing such agreements.

4.4. External Business Associates and Standard Contractors

There will continue to be relationships between DHHS divisions or offices and private/public external contractors/vendors who may or may not provide services, such as legal, accounting, management services and others. When those contractors/vendors that provide such services are given access to protected health information, they will be considered an External Business Associate. External Business Associates are not members of the covered health care component's workforce and they are not under the same legal entity. The revised DHHS standard contract that contains the required HIPAA language must be used by divisions or offices as a template in developing business associate agreements that are customized to each External Business Associate.

Example: QuadraMed as the vendor that maintains the HEARTS system utilized by the DMH/DD/SAS institutions, will be an External Business Associate since they are responsible for application development and support that necessitates access to PHI.

4.4.1. Identifying External Business Associates

Initially, each of the division or office's contracts need to be reviewed and evaluated as follows:

- 1) Does the contracted service affect the entire division or office (including the covered health care component)?

- 2) Does the contracted service affect only the covered health care component?
- 3) Does the contracted service not affect the covered health care component at all?
- 4) Is the service provided one of the services identified by HIPAA (see 6.1)?
- 5) Does the contracted service require the exchange of protected health information?

Conclusion: 1) If a service is provided for (or on behalf of) the covered health care component in any way, and 2) if protected health information is exchanged, this indicates a business associate relationship. If the evaluation does not support a business associate relationship, it should remain a standard contract.

After the initial categorizing of existing contracts, which will be a one-time occurrence, negotiations for all new contracts must include the determination of whether the service provided will require a business associate relationship or a standard contract.

Each covered health care component must determine the most efficient method for reviewing and assessing each of the division/office's current contracts. In most agencies, there is a Contracts Coordinator who is responsible for processing and maintaining a copy of all the agency's contracts. If there is no Contracts Coordinator in the agency, a team approach, including individuals who are responsible for contract negotiations may be needed.

5. Examples To Be Used As Guidance

This section is provided as guidance in determining:

- 1) Services and functions that require a business associate relationship;
- 2) Services and functions that generally do not require a business associate relationship; and
- 3) Services and functions that need to be carefully evaluated as these services may or may not require a business associate relationship based upon the exact services provided, and the use and disclosure of protected health information.

5.1. *Examples of Services and Functions that Require Business Associate Relationships*

The services listed in the left-hand column are identified in the HIPAA Regulations as those services for which a Business Associate relationship may be required. The items listed in the right-hand column are examples of activities or functions for which a Business Associate relationship may be required. This list is not exclusive, but does provide the most common functions or activities within the service categories.

Legal Services

Attorney Representing Agency

Actuarial Services

Benefits Management

Accounting Services

Patient Accounts Billing
Claims Processing
Claims Administration
Bill Collections

Consulting Services

Professional Services
Special Population Assessments (e.g.,
Olmstead interviews)

Data Aggregation Services

Data Analysis
Data Processing
Data Administration (InfoSystems Support)

Management Services

Practice Management
Software Support
Utilization Review
Quality Assurance
Contract Analysis
Central Office Supervision

Administrative Services

Security
Dietary
Machine Maintenance
Facility Maintenance
Landscaping
Housekeeping
Hardware Support
Audits/Surveys
Purchasing

Accreditation Services

JCAHO
Council on Accreditation

Financial Services

Re-pricing
Rate Setting

5.2. Examples of Services and Functions that May Not Require Business Associate Relationships

Providers of treatment (The “treatment exception” does not require a business associate relationship between two treatment providers, when the service rendered is **treatment only** and does not include other administrative services such as utilization review. For example, a business associate relationship may not exist between a DHHS covered health care component and a local hospital, when a client is referred for treatment).

Other Examples of Treatment Providers that may not require a business associate relationship:

- Physician Services
- Nursing Services
- Laboratory Services
- Radiology Services
- Physical Therapy
- Occupational Therapy
- Speech/Hearing Therapy
- Recreation Therapy
- Psychology Services
- Counseling
- Pharmacy
- Others (this list does not include all treatment-related services provided)

Note: Although the treatment exception is a specific exclusion in the Privacy Regulations, if a health care component already has a contract with a treatment provider, and there is any question as to whether or not anything other than treatment is provided, it is advisable to include the Business Associate language in the existing contract in order to assure protection of protected health information. When treatment services are routinely provided onsite at the covered health care component, the component may need to consider the treatment provider to be a member of the workforce.

Bank services (The “financial transactions exception” does not require a business associate relationship between a DHHS covered health care component and a bank. For example, a business associate agreement is not required between a DHHS covered health care component and a bank for transactions involving patients’ personal funds or for processing credit card payments by patients for health care services).

Courier services (A courier service or other postal service that transports medical records from a covered health care component to another entity is not a business associate of a DHHS covered component because it does not use or disclose the protected health information in its possession). This is a specific exclusion in the Privacy Regulations.

Maintenance services (Contracted services for facility maintenance such as tree-trimmers, carpet cleaners, landscapers, piano tuners and other services needed to maintain a facility or campus is not a business associate of a DHHS covered health care component when it does not use or disclose protected health information).

Administrative Services (Contracted services for administrative maintenance such as office machine maintenance, housekeeping services and telephone repair is not a business associate of a DHHS covered health care component when it does not use or disclose protected health information).

5.3. *Examples of Services and Functions that May or May Not Require Business Associate Relationships*

Third-Party Cleaning Service (A contracted cleaning service may or may not be under the “direct control” of a covered health care component. If staff under the direct control of a covered health care component provides cleaning services, they are considered a member of the workforce and must comply with agency policies and procedures. If cleaning services are provided by staff not under the direct control of a covered health care component, and although cleaning occurs in areas where protected health information is maintained the cleaning crew would not ordinarily use or disclose protected health information in the performance of their duties, in general, this would not require a business associate relationship. The control and extent of duties, as well as access to protected health information, will determine whether or not a business associate agreement is needed).

Board Members (Usually board members are not performing functions on behalf of a covered entity and are not part of the workforce, however, they may have access to protected health information when quality assurance and other patient issues reach the board level. Whether the board routinely has access to, uses or discloses protected health information needs to be considered when determining whether or not board members should be business associates. NOTE: If Board activities qualify as oversight, a business associate relationship would not be applicable).

Incidental Access (Other service providers that do not need to use or disclose protected health information to do their job, but do in fact have access to such information, will need to be evaluated as to whether or not protected health information should be protected through a business associate agreement).

6. Developing Agreements for Assuring Protection of Health Information

Once all business associate relationships have been identified and categorized, the type of required documentation must be determined.

6.1. *Division Business Associates Documentation*

HIPAA-compliant division or office policies and procedures must be in place and the covered health care component will need to maintain documentation verifying that each member of the workforce has been trained in and will comply with the HIPAA-compliant policies and procedures.

6.2. *DHHS Business Associate Documentation*

DHHS Directives that apply to all covered health care components and their business associates within the department will have to be in place so that policies and procedures for handling protected health information in each affected division or office will be consistent. The covered health care component will need to maintain documentation verifying that each member of the workforce has been trained in and will comply with HIPAA-compliant policies and procedures.

6.3. *State Government Business Associate Documentation*

A Memorandum of Understanding must be developed with each business associate from other state governmental departments. The MOU template developed by the DHHS Office of Purchase and Contracts must be used in developing each MOU. The DHHS template will contain the required HIPAA language that must be included in each MOU developed by the covered component. The specific information to be included in each MOU will depend upon the service provided and the extent of protected health information to be shared between a covered health care component and a business associate. The covered health care component is responsible for initiating the MOU process.

6.4. *External Business Associate Documentation*

A Business Associate Agreement (contract) must be developed with each external contractor/vendor. The External Business Associate Agreement developed by the DHHS Office of Purchase and Contracts must be used in developing each Agreement. The DHHS template will contain the required HIPAA language that must be included in each Agreement developed by the covered component. The specific information to be included in each Agreement will depend upon the service provided and the extent of protected health information to be shared between a covered health care component and a business associate. The covered health care component is

responsible for initiating the Business Associate Agreement (contract) process.
NOTE: It is the responsibility of all Business Associates to assure that all of their sub-contractors are aware of HIPAA requirements.

6.5. Standard DHHS Contracts

Contracts for independent contractors to perform services requiring specialized knowledge or experience must continue to be documented, using the DHHS standard contract, in accordance with the DHHS Purchase and Contracts Manual.

7. Business Associate Matrices

In an effort to reduce the confusion in identifying business associates, the PMO will provide each covered health care component with an Excel workbook for collecting this information by categories of business associates. The workbook will be used to identify business associate relationships with individuals or agencies that provide specific services on behalf of a covered health care component and each workbook is customized for each covered health care component. Divisions, Offices and SOEs may be able to utilize information contained on the summary Information Flow Assessment, Part F: Business Associate Identification. The summary report can be printed from the DHHS HIPAA Website. The document “Using the Business Information Flow Assessment” contains instructions for accessing the summary report and is located at <http://dirm.state.nc.us/hipaa/newsite/focusgroup/operation/IFA.html>

7.1. Workbook Content

Each workbook contains 4 spreadsheets with the following tabs:

- External Business Associates
- Division Business Associates
- DHHS Business Associates
- State Government Business Associates

Within each spreadsheet, information to be captured includes name of the individual/agency that performs a service on behalf of the covered health care component, service(s) provided, an indication if protected health information is exchanged, an indication if the individual/agency meets the business associate criteria, and space for comments, notes or further specification.

7.2. Spreadsheet Instructions

Each covered health care component must complete each spreadsheet in the workbook. However, if there is more than one covered health care component within a Division central office (e.g., in DMH/DD/SAS, both Adult Services and Adolescent Services in the Substance Abuse Section are covered health care components) only one External Business Associate spreadsheet will have to be completed. Complete information in the columns as follows:

COLUMN	INSTRUCTIONS
A	Identify the name of the individual/agency or workgroup within an agency that performs one of more services on your behalf. Division workgroups (as specified on the Information Flow Assessment Workgroup verification sign-off) are pre-filled. DHHS divisions, offices and SOEs are pre-filled. Non-DHHS state government departments and major divisions within each department are pre-filled. Covered health care components are encouraged to utilize the business associate information that was collected during the Information Flow Assessment (BIFA) process to complete this column. The summary BIFA can be printed from the DHHS HIPAA web site.
C-K	Place an 'X' in the appropriate column, denoting the type of service the workgroup provides on your behalf.
L&M	If the service provided is for treatment, place an 'X' in the appropriate column, denoting if the service is treatment only or if the treatment service includes additional services such as utilization review.
N	Place an 'X' in this column if there is a service provider that you are uncertain as to the relationship that exists. Explain briefly in the 'Comments' column.
P-R	These columns denote whether or not PHI is exchanged with this service provider. If PHI is exchanged, place an 'X' in the appropriate column, denoting whether the exchange is electronic or paper/oral. If the exchange is both electronic and paper/oral, place a check in both columns. If no PHI is exchanged, place an 'X' in column R, "No".
T	A check in this column will indicate that the agency/contractor will be considered a member of covered health care component's workforce.
U	A check in any of the columns C-K, column M and columns P-Q equals a business associate relationship so place an 'X' in the column if all factors are met.
V	Include any free text comments.

7.3. *Workbook Distribution*

Each covered health care component will need to retain the workbook as part of HIPAA due diligence documentation. The completed workbook shall also be sent to the DHHS HIPAA PMO. The PMO will review the workbook findings and any questions resulting from the review will be referred to the appropriate division or office HIPAA Coordinator.

7.4. *Business Associate Verification*

The PMO will send verification letters to each DHHS Business Associate and Division Business Associate identified by the covered health care components. They will be asked to verify that there is a Business Associate relationship with

the covered health care component. Once the verification is received, the Impact Determination Matrix will be updated to reflect all DHHS Business Associates and Division Business Associates since they will be considered a member of the component's workforce and must comply with HIPAA regulations.

End of Document