

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page of 1 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		Effective Date: April 14, 2003	
Originator: John Bianconi, Acting Privacy Official Department of Health and Human Resources		Assistant Secretary for Operations: Date:	
Secretary of DHHR:		Date:	

1.0 PURPOSE

The purpose of this Policy is to set forth the Department of Health and Human Resources (DHHR) procedure for Designation of Covered Health Care Components: Hybrid Entity in compliance of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

2.0 SCOPE

This policy applies to all employees, personnel from other organizations contracting personnel, and vendors of DHHR.

3.0 APPLICABLE DOCUMENTS/MATERIAL

- 3.1 Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- 3.2 Reference: Federal regulations 45 CFR §§ 164.504(b), (c), and (g);
45 CFR 164.530(j)

4.0 RESPONSIBILITY/REQUIREMENT

- 4.1 Designated Attorney, DHHR Privacy Official, Director Office of Personnel Services, Director of Management Information Services

4.2 Background: as follows

4.2.1 The administrative simplification section of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) applies to any organization that performs the covered health care functions of a *health plan, health care clearinghouse, or health care provider* that conducts electronically any of the *standard transactions* (See DEFINITIONS for the terms in italics). This is true even if the organization's principal activity or mission is not related to these health care functions.

4.2.2 HIPAA regulations allow any organization to separate its covered health care functions from its other functions. An organization that makes this separation is a "hybrid entity."

4.2.2.1 A *hybrid entity* is a single legal entity:

4.2.2.1.1 That performs any of the covered health care functions;

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page 2 of 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		Effective Date: April 14, 2003	

- 4.2.2.1.2 Whose business activities include both covered and non-covered functions; and
- 4.2.2.1.3 That designates covered health care components in accordance with this **policy**.
- 4.2.2.2 Covered health care components **are units** of the hybrid entity that would be covered by HIPAA if they were separate legal entities. A component that meets the definition of *health plan* (ERISA employee health benefit plans are treated as separate legal entities: **they are not part of a hybrid entity**), *provider of health care* that **conducts** HIPAA transactions **electronically**, or *health care clearinghouse* is a **covered health care component**.
- 4.2.2.3 If a non-covered component **of the** entity performs support services **for a covered health care component**, the functions that perform **these support services** should be designated as part of the covered component, if the services involve *business associate functions*. **In other words**, functions that involve **receiving PHI from, or creating PHI** for, a health care component **should be designated as part of** the health care component in a **hybrid** entity. (See DEFINITIONS and DISCLOSURE OF PROTECTED HEALTH INFORMATION TO BUSINESS ASSOCIATES AND OTHER CONTRACTORS **policy** regarding business associates.)
- 4.2.2.4 **If the unit** provides services for both a covered health care component and for other components, this policy applies only to **health information** that it receives or creates in support of the **covered health care component**. Only the support services provided to the covered component can be designated.
- 4.2.2.5 If the service function is designated as part of the covered health care component, it is not necessary to document the relationship between them with a business associate agreement. The entire covered health care component, including the service function provided by another component, is subject to federal HIPAA privacy regulations and this policy. Failure to include the "business associate" function in the designated covered component would mean that any transfer of PHI to it would be a disclosure, and subject to the same rules as disclosure to an outside entity. HIPAA rules do not allow an intra-entity business associate contract between a covered component and a non-covered function, unless both components are government entities.

<i>Document:</i> POLICY	<i>Document Number:</i> 0431	<i>Revision:</i> DRAFT	Page 3 of 10
<i>Subject:</i> DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		<i>Effective Date:</i> April 14, 2003	

4.2.2.6 A hybrid entity must designate which of its components are covered health care components subject to HIPAA. The covered health care components must comply with applicable HIPAA administrative simplification regulations, including the adoption of HIPAA compliant policies and procedures. The other components of the hybrid entity are not subject to HIPAA regulations, and the Department of health and Human resources(DHHR) may develop policies for these components regarding the privacy and security of information without regard to federal HIPAA regulations.

4.2.2.7 The hybrid entity must also implement safeguards to prevent protected health information from crossing the boundary between covered health care components, or between a covered component and other components, if such a use or disclosure of PHI would be contrary to HIPAA regulations if the components were separate legal entities.

4.3 Policy: DHHR hereby designates itself a hybrid entity, within the meaning of 45 CFR § 164.504(a).

4.3.1 Designation of Covered Health Care Components

The following components of DHHR are designated as covered health care components that are subject to HIPAA administrative simplification regulations:

4.3.1.1 HIPAA Covered Components Under DHHR Hybrid Structure:

- 4.3.1.1.1 Secretary's Office is a Business Associate with EEO/Affirmative Action Unit voluntarily covered. The Catastrophic Illness Commission and Commission for the Deaf and Hard of Hearing are Business Associates.
- 4.3.1.1.2 Bureau for Medical Services (BMS) is a Health Plan
- 4.3.1.1.3 Bureau for Behavioral Health and Health Facilities (BHBF) is a Provider (7 facilities) and is a Business Associate of BMS (i.e., MR/DD Waiver Program). The Ombudsman for Behavioral Health is a Business Associate.
- 4.3.1.1.4 Bureau for Children and Families (Business Associate)
- 4.3.1.1.5 Bureau of Public Health defines the Family Planning Program and the Commissioner's Office as a Business Associate.

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page 4 of 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		Effective Date: April 14, 2003	

- 4.3.1.1.6 Bureau for Finance (Business Associate except for the Office of Budget Planning and Management).
- 4.3.1.1.7 Management Information Services (Business Associate)
- 4.3.1.1.8 Bureau for Child Support Enforcement is a Business Associate except for their Personnel, Public Awareness, Central Services, Financial Services and Adjustment Unit components.

4.3.2 **Applicability of Regulations, Policies and Procedures**

DHHR has determined that the covered health care components designated above are subject to the administrative simplification regulations of HIPAA, 45 CFR Parts 160, 162, and 164. Policies and procedures for each component will be adopted, implemented, and maintained to achieve compliance with those regulations.

4.3.3 **Safeguards**

The following safeguards are adopted to protect health information in the custody of the health care components from being inappropriately disclosed to or used by other components:

4.3.3.1 Members of the workforce (*workers*) who are assigned to duties with the covered health care components will not be assigned to duties with other components or functions, to the extent that this separation of duties is practicable. This includes workers assigned to other components, who provide support services to a covered health care component.

4.3.3.2 Workers will not be assigned to perform duties for more than one type of health care component (health plan, health care provider, or health care clearinghouse) to the extent practicable.

4.3.3.3 Workers who are assigned to covered health care components, or who provide support services to a covered component, will receive training in maintaining the security and privacy of protected health information in accordance with DHHR's policies and procedures.

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page 5 of 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		Effective Date: April 14, 2003	

4.3.3.4 Workers who are assigned to both covered health care components and other components, or to more than one type of health care component, will receive additional training in the importance of maintaining the confidentiality of protected health care information. The training will stress prohibited disclosures and uses of PHI.

4.3.3.4.1 Information that pertains to an individual as a member of a health plan component may not be disclosed to or used by a health care provider component, unless the individual is also a *patient* of the health care provider component, and *vice versa*.

4.3.3.4.2 Protected health information may be used by the worker in his or her capacity as a worker for the covered health care component, subject to applicable DHHR policies and procedures.

4.3.3.4.3 Protected health information may be used or disclosed by the worker in his or her capacity as a worker for another component, that is not a covered health care component, only to the extent that disclosure to the other component is permitted under applicable DHHR policies and procedures that govern the disclosure of PHI.

4.3.3.5 Health care records of covered health care components will be separated from other records by physical and electronic barriers, to the extent practicable.

4.3.3.6 Supervisors of covered health care components and other components that receive or create health information will be trained to watch for instances where protected health information has inappropriately crossed the boundary between a covered health care component and another component, and to take steps to correct the situation and prevent a recurrence. This includes improving training and operating procedures, and may include disciplinary action.

4.3.3.7 Any instance of PHI crossing the boundary between a covered health care component and another component in violation of DHHR policies must be reported to the DHHR Privacy Official. This disclosure must be recorded, and must be included in any accounting of disclosures to the individual. See ACCOUNTING OF DISCLOSURES OF PROTECTED HEALTH INFORMATION policy.

<i>Document:</i> POLICY	<i>Document Number:</i> 0431	<i>Revision:</i> DRAFT	Page 6 of 10
<i>Subject:</i> DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		<i>Effective Date:</i> April 14, 2003	

4.4 Procedure: as follows

- 4.4.1 The DHHR Privacy Official will work with the Bureau HIPAA Designated Coordinators and Designated Attorneys who represent members of the DHHR management team to assure that policies and procedures are adopted for the covered health care components in compliance with the requirements of HIPAA administrative security regulations (“HIPAA requirements,” 45 CFR §§ 160, 162, and 164).
- 4.4.2 The DHHR Privacy Official and Bureau Designated HIPAA Coordinators will assure that adequate training in DHHR’s policies and procedures that relate to HIPAA requirements is provided to members of the workforce assigned to each designated covered health care component, and to workers assigned to other components, as appropriate to implement appropriate safeguards to prevent the misuse and inappropriate disclosure of PHI.
- 4.4.3 The DHHR Privacy Official and Bureau Designated HIPAA Coordinators will work with the Director of Personnel Services and other members of DHHR management as appropriate, to develop remedial procedures and sanction policies, to ensure that policies and procedures that relate to HIPAA requirements are followed.
- 4.4.4 The DHHR Privacy Official, Bureau Designated HIPAA Coordinators, DHHR Security Officer, Director of Management Information Services, and Director of Medical Records will implement physical and electronic barriers between health information that is in the custody of covered health care components and health information that is in the custody of other components, and between health information records that are in the custody of covered health care components of different types (health plan, provider, or clearinghouse).

5.0 DEFINITIONS

- 5.1 Health plan Brief definition: “Health plan” means an individual or group plan that provides, or pays the cost of, medical care. See the definition of “medical care,” below:
- 5.1.1 Detailed definition: Health plans include all of the following:
- 5.1.1.1 A group health plan, which is the same as an employee welfare benefit plan as defined in the federal Employee Retirement Income Security Act (ERISA), to the extent that the plan provides or pays for medical care.

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page 7 of 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY			Effective Date: April 14, 2003

5.1.1.2 A health insurance issuer, which means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a state and is subject to state law that regulates insurance.

5.1.1.3 An HMO, which means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO. [In some states, HMOs are licensed as insurance companies. In other states, HMOs operate under a license or certificate of authority that is unique to HMOs. In either case, an HMO is considered a "health plan."]

5.1.1.4 Medicare, which means Part A or Part B of title XVIII of the U. S. Social Security Act.

5.1.1.5 Medicaid, which means title XIX of the U. S. Social Security Act.

5.1.1.6 A company that issues Medicare supplemental policies, even if it is not otherwise a health insurance issuer or HMO.

5.1.1.7 A company that issues long-term care policies, even if it is not otherwise a health insurance issuer or HMO. Exception: if the company only issues nursing home fixed-indemnity policies, and does not otherwise meet the terms of this definition, it is not considered a "health plan."

5.1.1.8 A Multi-Employer Welfare Arrangement (MEWA) or any other employee welfare benefit plan or other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

5.1.1.9 The health care program for active military personnel under title 10 of the United States Code.

5.1.1.10 The veterans' health care program under title 38 chapter 17 of the United States Code.

5.1.1.11 CHAMPUS: The Civilian Health and Medical Program of the Uniformed Services.

<i>Document:</i> POLICY	<i>Document Number:</i> 0431	<i>Revision:</i> DRAFT	Page 8 of 10
<i>Subject:</i> DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		<i>Effective Date:</i> April 14, 2003	

- 5.1.1.12 The Indian Health Service program under the Indian Health Care Improvement Act.
 - 5.1.1.13 The Federal Employees Health Benefits Program (FEHBP)
 - 5.1.1.14 An approved State child health plan under title XXI of the U. S. Social Security Act.
 - 5.1.1.15 The Medicare+Choice program under Part C of title XVIII of the U. S. Social Security Act.
 - 5.1.1.16 A high risk pool established under state law to provide health insurance coverage or comparable coverage to eligible individuals.
 - 5.1.1.17 Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care.
- 5.1.2 The following are NOT “health plans” for purposes of federal privacy regulations:
- 5.1.2.1 Policies that provide coverage only for accident, and/or disability income insurance.
 - 5.1.2.2 Coverage issued as a supplement to liability insurance.
 - 5.1.2.3 Liability insurance, including general liability insurance and automobile liability insurance.
 - 5.1.2.4 Workers' compensation or similar insurance.
 - 5.1.2.5 Automobile medical payment insurance.
 - 5.1.2.6 Credit-only insurance.
 - 5.1.2.7 Coverage for on-site medical clinics.
 - 5.1.2.8 Other similar insurance coverage under which benefits for medical care are secondary or incidental to other insurance benefits.
 - 5.1.2.9 A government-funded program that does not meet any of the definitions above, and

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page 9 of 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		Effective Date: April 14, 2003	

5.1.2.9.1 Whose principal purpose is other than providing, or paying the cost of, health care; or

5.1.2.9.2 Whose principal activity is:

5.1.2.9.2.1 The direct provision of health care to persons; or

5.1.2.9.2.2 The making of grants to fund the direct provision of health care to persons.

5.2 Health care clearinghouse: A public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value-added” networks and switches, that does either of the following functions:

5.2.1 Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into *standard data elements* or a standard transaction.

5.2.2 Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

5.3 Provider of health care: Any person or organization which furnishes, bills, or is paid for health care services in the normal course of business.

5.4 Standard transactions: Transactions for which the Secretary of the Department of Health and Human Services has adopted national standards, as follows:

5.4.1 Health care claims or equivalent encounter information

5.4.2 Health care payment and remittance advice

5.4.3 Coordination of benefits

5.4.4 Health care claim status

5.4.5 Enrollment and disenrollment in a health plan

5.4.6 Eligibility for a health plan

5.4.7 Health plan premium payments

5.4.8 Referral certification and authorization

5.4.9 First report of injury

5.4.10 Health claims attachments

5.4.11 Other transactions that the Secretary HHS may prescribe by regulation.

5.5 Business associate : A person or organization that performs a function or activity involving the use or disclosure of protected health information, on behalf of DHHR. A person or organization who only assists in the performance of the function or activity is also a *business associate*. This includes a person or organization that receives PHI from DHHR, and one who obtains PHI for DHHR. This includes, for example: data analysis, processing or administration; web site

Document: POLICY	Document Number: 0431	Revision: DRAFT	Page 10 of 10
Subject: DESIGNATION OF COVERED HEALTH CARE COMPONENTS: HYBRID ENTITY		Effective Date: April 14, 2003	

- 5.6 hosting; utilization review; quality assurance; billing; collections; benefit management; practice management; legal services; actuarial services; accounting and auditing; consulting; management and administrative services; accreditation; financial services; or any other service in which the person or organization obtains PHI from or for DHHR. Members of the *workforce* are not considered business associates. The exchange of *protected health information* between providers of health care, for purposes of providing treatment to a patient, does not create a business associate relationship.
- 5.7 Protected Health Information (PHI): Information, including demographic information, whether oral or recorded in any form or medium, that relates the individual's health, health care services, or payment for services and which identified the individual.
- 5.8 Use : With respect to protected health information, the sharing, employment, application, utilization, examination, or analysis of such information within DHHR. SEE ALSO "Disclosure."
- 5.9 Disclosure: the release, transfer, provision of access to, or divulging in any other manner of information outside DHHR. SEE ALSO "Use."
- 5.10 Workforce: (*workers*) Employees, volunteers, trainees, and other persons whose conduct, in the performance of work for DHHR, is under the direct control of DHHR, whether or not DHHR pays them.
- 5.11 Patient: Any individual about whom DHHR has created or received individually identifiable health information.
- 5.12 Vice versa: With the order reversed.