

**NYS Central HIPAA Coordination Project
HIPAA Applicability Evaluation**

Name of the Agency:		
Page Number:		
Overall Agency Designation (Choose those that apply):		
<input type="checkbox"/> Non-covered <input type="checkbox"/> Health care plan <input type="checkbox"/> Health care clearinghouse <input type="checkbox"/> Health care provider engaging in electronic transactions <input type="checkbox"/> Hybrid <input type="checkbox"/> Organized health care arrangement <input type="checkbox"/> Affiliated entity <input type="checkbox"/> Business associate/partner		
Reasoning Behind Determination:		
Agency Contact Name:		Agency Contact Phone Number:
Individual Functions Reviewed	Designation of Function	Summary of Reasoning
	non-covered	
	non-covered	
	non-covered	
	non-covered	
	non-covered	
Signature of Agency Commissioner or Equivalent and Date of Submission:		

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Transactions Standards and Privacy/Security Standards

Requirements: Overall, a **Covered Entity** must:

1. Protect the privacy and security of individually-identifiable health information, in conformance with the HIPAA statute and regulations, and;
2. Use only the Standard Transaction format and data content for any of the Covered Transactions that it exchanges electronically (by any electronic methodology, including but not limited to file transfers, voice response, web-based entry, and other technologies). See the definitions of the Covered Transactions in the Health Care Provider column (boxes 2c – 12c) below.

Your Agency's HIPAA-status Determination: The determination of whether your agency is a Covered Entity, or has another HIPAA-impacted status, and the extent to which and what type, is ultimately a legal conclusion, and you should work closely with your agency's legal counsel in drafting your determination letter.

Covered entities are directly regulated by HIPAA, and there are three general categories: **(1) health care plans; (2) health care clearinghouses, and (3) health care providers who engage in any of a set of HIPAA-defined standard electronic health care transactions.** Depending on how each of these types of entities can be divided up or combined together, they may form a particular type of covered entity, such as a **hybrid entity; an affiliated entity, or an organized health care arrangement.**

You might find it helpful to start with the definitions of each Covered Entity that are given in the chart below:

- If your agency is described in any of boxes 1.0a through 17a, and is NOT described in boxes 18a through 23a, **it is likely a Health Plan Covered Entity.**
- If your agency is described in boxes 1.0b and 1.1b, **it is likely a Health Care Clearinghouse Covered Entity.**
- And if your agency is described in boxes 1.0c, and provides health care services as described in 1.1c, and electronically conducts any of the transactions listed in 2c through 12c, **it is likely a Health Care Provider Covered Entity.** Remember that “electronic” conduct of any of the transactions includes not only file transfers (as are usually done with claims submission), but all other non-paper, non-human-based means of communication. For example, if an entity uses the Voice Response or card-

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swipe units to check a member's eligibility, it is conducting an electronic transaction.

Particular Types of Covered Entities

Hybrid Entities: It is possible that while doing this analysis you will find that while there may be "Covered Entity" functions within your agency in particular department(s) or program(s), other aspects of what the agency does would not ordinarily be considered as "covered". HIPAA requires that each of these components be evaluated separately, according to their respective functions. If the component that provides the services is not itself an entity with a separate legal status (for example, if it is a department of a state agency, but not a state agency itself), then the entity to which it belongs is likely a HIPAA "**hybrid entity**", and HIPAA's rules would apply to the component(s) that perform the covered function(s). The importance of being a hybrid entity is that HIPAA requires the entity to build walls between the covered functions and the rest of the entity, so that the non-covered portions do not have access to Protected Health Information. In its most recent proposed modification to the HIPAA privacy regulation, DHHS recommended that, to determine if an entity's function is a "covered function" or not, the entity envision the function in question as if it were a stand-alone entity, and analyze whether, standing alone, it would fall within one of the three types of covered entities (health care plans, clearinghouses, and certain health care providers). If, standing alone, it would, then the function can be considered a covered function.

As an example of how this might play out in practice, if your agency has determined that the majority of its functions are not Covered Entity functions, your agency might next turn to its Human Resources functions to discern whether those members of your workforce handle Protected Health Information ("PHI"). You might first identify your agency's Human Resources functions where PHI is handled (for example: employee benefits; Employee Health Service ("EHS"); and Employee Assistance Program "EAP"). Then, you might envision each of these functions as though it were a separate entity, and determine whether, in that instance, it would meet one of the three types of "Covered Entities". The EAP's employees, for example, may not be health care providers at all, or, even if they are, in their capacity in the EAP they may be engaged only in making referrals, and not the provision of health care, and thus would not, standing alone, be considered a Covered Entity. In the EHS, some members of the workforce may be health care providers, and, under DHHS's definitions, may be engaged in the performance of health care. However, if all of their record-keeping is on paper and these providers do not engage in the HIPAA-defined electronic transactions, then they would not be Covered Entities under HIPAA. Finally, concerning Employee Benefits, while Benefits Administrators may handle PHI as part of their duties in relation to the NYS Health Insurance Plan, the NYSHIP may be more reasonably conceptualized as a single health plan, and

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the activities of Benefits Administrators the functions of an employer, not of a Covered Entity.

Organized health care arrangements (OHCAs): The HIPAA privacy regulation allows, for efficiency's sake, two or more distinct covered entities with separate legal identities who have created a single health care program which is sufficiently clinically or operationally integrated to make it necessary for the entities to be share policies and procedures for the joint management and operations of the arrangement, and which appears to the public to be a single program, to meet the HIPAA requirements using uniform HIPAA forms, policies and procedures. Your agency may want to take advantage of this definition in its current or future health care programs developed jointly with other agencies, or with others.

Affiliated Entities: The HIPAA regulations also recognize other complexities in organizational governance, such as affiliated entity structures. Affiliated covered entities, under HIPAA, are covered entities which are legally distinct, but which share common ownership or control. An example might be an academic medical center with a separate hospital and medical college (two legally distinct entities) but with shared control by an umbrella organization (a medical "center"). As with OHCAs, the regulations allow these types of separate, but connected, covered entities to share common HIPAA forms and policies.

Your Agency's HIPAA-status: Non-Covered Entities Which Might Nevertheless be Impacted by HIPAA:

Business Associates (Privacy Regulation) and Business Partners (Security Regulation) are entities which are not directly regulated by HIPAA, but to whom HIPAA requirements pass through by the contracts or Memoranda of Understanding which HIPAA requires that Covered Entities have in place with those partners who perform services for them. For example, if your Agency is not otherwise a Covered Entity, but it provides legal counsel to another agency which is a Covered Entity, and during the course of that representation that Covered Entity shares Protected Health Information with your agency, your agency would most likely meet the definition of a "Business Associate" to the Covered Entity-agency, which, under HIPAA, would be required to have in place with your agency a contract, Memorandum of Understanding or other satisfactory assurances that your agency will keep that information confidential.

As another example, if your agency is a Covered Entity and it contracts with another state agency, or with an outside vendor, for that vendor to secure your agency's Protected Health Information (for example, in a computerized database), that outside entity is most likely your Business Associate/Business Partner under HIPAA. While HIPAA does not directly regulate their behavior, HIPAA would require your agency to have privacy and/or security agreements in

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place with that other entity, so that you pass-through to them HIPAA protections by operation of your contract or other arrangement.

Exceptions: Note that not all non-covered parties to such "outsourcing" arrangements are Business Associates. HIPAA's Privacy Regulation makes an exception for associates it refers to as "conduits". The regulation defines a "**conduit**" as an associate that "transports information but does not access it other than on a random or infrequent basis as may be necessary for the performance of the transportation service, or as required by law." The regulation also makes an exception to the Business Associate requirements for **financial institutions** that process "consumer-conducted financial transactions". For example, if a credit card is used to make payment to an HIV Clinic, although the circumstances surrounding that financial transaction may concern health information, DHHS would not consider the credit card issuer to be a "Business Associate" of the HIV Clinic.

It should be clear that these HIPAA definitions are complex, and may not always be clear-cut in all situations. Even if the exercise proves difficult, there is great value for your agency in making and documenting its reasonable determinations: in fact, doing so is required by law. For example, the HIPAA privacy regulation REQUIRES that certain designations made by your agency, such as a determination that your agency is a "hybrid entity" (164.504(c)(2)(iii), or an "affiliated entity" (164.504(d)(2)(ii), be documented in accordance with the regulation's documentation provisions (164.530(j)).

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	(a) Health Plan	(b) Health Care Clearinghouse	(c) Health Care Provider
1.0	<p>A Health Plan is an individual or group plan that provides, or pays the cost of, medical care. Health Plans are further defined in lines 1.1a through 17a. Specific exclusions are given in blocks 18a through 23a below. <i>Be sure to check the exclusions in blocks 18a through 23a before you make your decision.</i></p>	<p>A Health Care Clearinghouse is 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:</p>	<p>A Health Care Provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter is a Covered Entity. Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of 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.</p>
1.1	<p>A group health plan [defined as an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise,</p>	<p>(1) Processes or facilitates the processing of health information received from another entity in a non-standard format or containing nonstandard data content into standard data elements or a standard transaction, or (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or</p>	<p>Health care means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.</p>

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(b) Health Care Clearinghouse		
(a) Health Plan	(b) Health Care Clearinghouse	(c) Health Care Provider
<p>2 A health insurance issuer [defined as 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. Such term does not include a group health plan.]</p>		<p>§ 162.1101 Health care claims or equivalent encounter information transaction.</p> <p>The health care claims or equivalent encounter information transaction is the transmission of either of the following:</p> <p>(a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care. [Claim]</p> <p>(b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care. [Encounter]</p>
<p>3 An HMO [defined as 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.]</p>		<p>§ 162.1201 Eligibility for a health plan transaction.</p> <p>The eligibility for a health plan transaction is the transmission of either of the following:</p> <p>(a) An inquiry from a health care provider to a health plan, or from one health plan to another health plan, to obtain any of the following information about a benefit plan for an enrollee: (1) Eligibility to receive health care under the health plan. (2) Coverage of health care under the health plan. (3) Benefits associated with the benefit plan.</p>

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	(a) Health Plan	(b) Health Care Clearinghouse	(c) Health Care Provider
4	Part A or Part B of the Medicare program under title XVIII of the Act.		(b) A response from a health plan to a health care provider's (or another health plan's) inquiry described in paragraph (a) of this section.
5	The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.		<p>§ 162.1301 Referral certification and authorization transaction.</p> <p>The referral certification and authorization transaction is any of the following transmissions:</p> <p>(a) A request for the review of health care to obtain an authorization for the health care.</p> <p>(b) A request to obtain authorization for referring an individual to another health care provider.</p> <p>(c) A response to a request described in paragraph (a) or paragraph (b) of this section.</p>
6	An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).		<p>§ 162.1401 Health care claim status transaction.</p> <p>A health care claim status transaction is the transmission of either of the following:</p> <p>(a) An inquiry to determine the status of a health care claim.</p> <p>(b) A response about the status of a health care claim.</p>
7	An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.		<p>§ 162.1501 Enrollment and disenrollment in a health plan transaction.</p> <p>The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information to a health plan to establish or terminate insurance coverage.</p>

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	(a) Health Plan	(b) Health Care Clearinghouse	(c) Health Care Provider
8	An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.		<p>§ 162.1601 Health care payment and remittance advice transaction.</p> <p>The health care payment and remittance advice transaction is the transmission of either of the following for health care:</p> <p>(a) The transmission of any of the following from a health plan to a health care provider's financial institution:</p> <p>(1) Payment (2) Information about the transfer of funds. (3) Payment processing information.</p>
9	The health care program for active military personnel under title 10 of the United States Code.		<p>(b) The transmission of either of the following from a health plan to a health care provider:</p> <p>(1) Explanation of benefits (2) Remittance advice.</p>
10	The veterans health care program under 38 U.S.C. chapter 17.		<p>§ 162.1701 Health plan premium payments transaction.</p> <p>The health plan premium payment transaction is the transmission of any of the following from the entity that is arranging for the provision of health care or is providing health care coverage payments for an individual to a health plan: (a) Payment (b) Information about the transfer of funds. (c) Detailed remittance information about individuals for whom premiums are being paid.</p>
11	The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)(as defined in 10 U.S.C. 1072(4)).		<p>(d) Payment processing information to transmit health care premium payments including any of the following:</p> <p>(1) Payroll deductions (2) Other group premium payments. (3) Associated group premium payment</p>

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	(a) Health Plan	(b) Health Care Clearinghouse	(c) Health Care Provider information.
12	The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.		<p>§ 162.1801 Coordination of benefits transaction.</p> <p>The coordination of benefits transaction is the transmission from any entity to a health plan for the purpose of determining the relative payment responsibilities of the health plan, of either of the following for health care: (a) Claims (b) Payment Information</p>
13	The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.		
14	An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.		
15	The Medicare + Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.		
16	A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals. [High-risk pools, as described in this rule, do not include any program established under state law solely to provide excepted benefits. For example, a state program established to provide		

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	(a) Health Plan	(b) Health Care Clearinghouse	(c) Health Care Provider
	workers' compensation coverage is not considered a high-risk pool under the rule.]		
17	Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).		
18	<i>Excluding workers' compensation and automobile insurance carriers, other property and casualty insurers, and certain forms of limited benefits coverage, even when such arrangements provide coverage for health care services.</i>		
19	<i>Excluding issuers of nursing home fixed-indemnity policies</i>		
20	<i>Excluding any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits (my note: such as workers' comp) that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and</i>		

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(b) Health Care		
(a) Health Plan	Clearinghouse	(c) Health Care Provider
21	<p><i>Excluding any government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition) whose principal purpose is other than providing, or paying the cost of, health care [but which do incidentally provide such services. For example, programs such as the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Food Stamp Program, which provide or pay for nutritional services, are not considered to be health plans.]</i></p>	
22	<p><i>Excluding any government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition) whose principal activity is (1) The direct provision of health care to persons; or (2) The making of grants to fund the direct provision of health care to persons. Examples include the Ryan White Comprehensive AIDS Resources Emergency Act, government funded health centers and immunization programs. (Note: Some of these may meet the rule's definition of health care provider.)</i></p>	

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		(b) Health Care Clearinghouse	(c) Health Care Provider
(a) Health Plan			
23	<p><i>Excluding agencies that determine eligibility for or enrollment in a health plan that is a government program providing public benefits (such as Medicaid or SCHIP) when that agency is not the agency that administers the program. For example, an agency that is not otherwise a Covered Entity, such as a local welfare agency, is not considered to be a Covered Entity because it determines eligibility or enrollment or collects enrollment information as authorized by law. We also do not consider the agency to be a business associate when conducting these functions.</i></p>		