

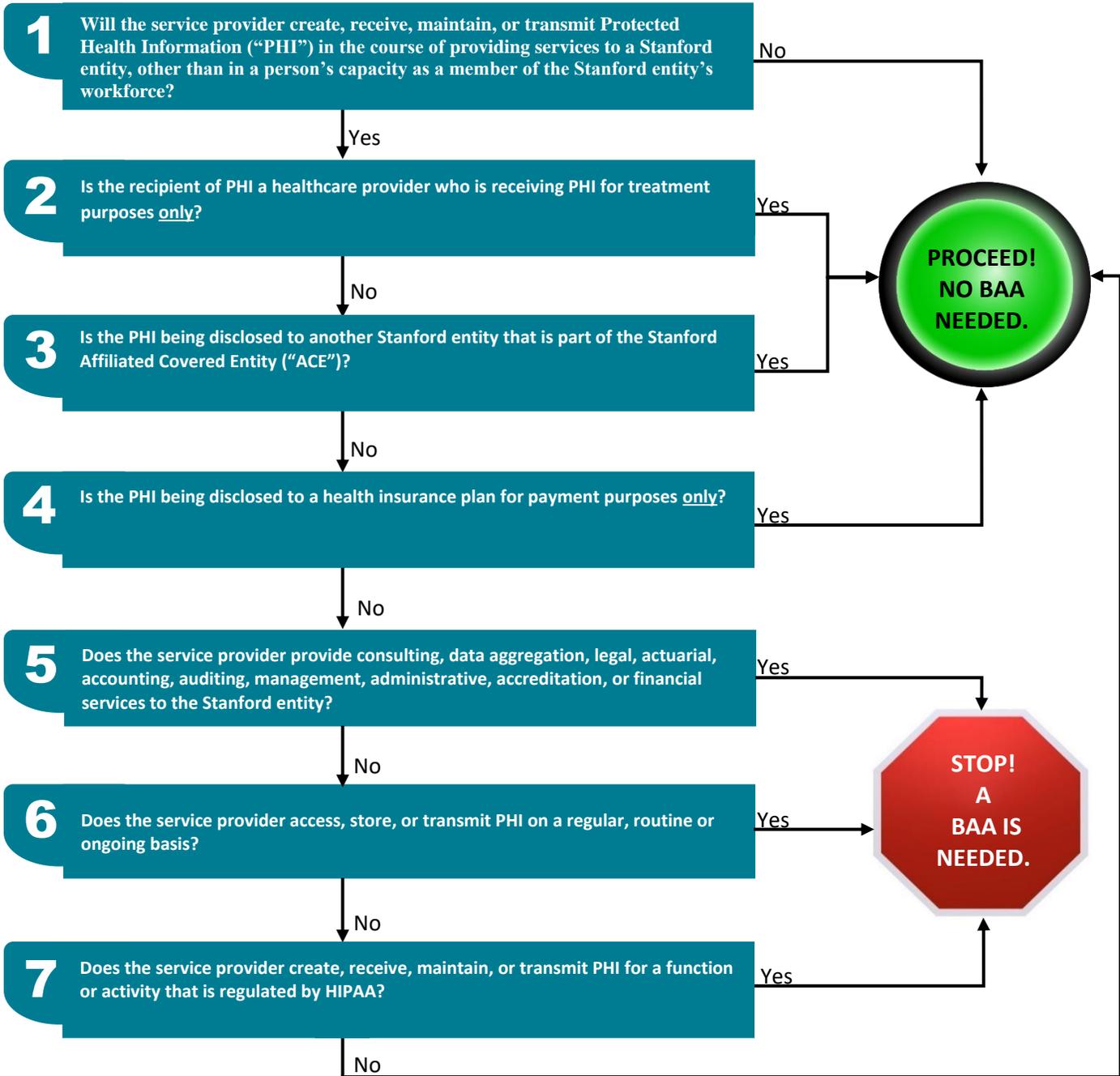


Stanford Contract HEALTH CARE Administration

Contract Administration is a shared service for the following legal entities: 1) Stanford Health Care; 2) Lucile Salter Packard Children’s Hospital at Stanford (“Lucile Packard Children’s Hospital” or “Stanford Children’s Health”); 3) The Hospital Committee for the Livermore-Pleasanton Areas (“Stanford Health Care – ValleyCare”); 4) Stanford University Medical Network Risk Authority, LLC (“The Risk Authority”); 5) University HealthCare Alliance; 6) Packard Children’s Health Alliance; 7) Stanford Health Care Advantage; 8) Stanford Blood Center, LLC; 9) CareCounsel, LLC

BUSINESS ASSOCIATE DECISION TREE

This Business Associate Decision Tree is designed to assist in determining whether the Vendor (Other Party) providing services to a Stanford entity is a “Business Associate” under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and if a Business Associate Addendum (“BAA”) will be required with such Vendor (Other Party). A “Business Associate” is a person or entity that performs certain functions or activities that involve the use or disclosure of Protected Health Information on behalf of, or provides services to, a covered entity. This decision tree is intended to serve as a general guideline and does not address every possible situation that could arise; for specific questions regarding the need for a BAA, please contact Contract Administration at ContractAdministration@stanfordhealthcare.org or the Privacy and Compliance Office at privacyofficer@stanfordhealthcare.org.



DEFINITIONS

1. ***Will the Vendor (Other Party) create, receive, maintain, or transmit Protected Health Information (“PHI”) in the course of providing services to a Stanford entity, other than in a person’s capacity as a member of the Stanford entity’s workforce? If “Yes,” continue to Question 2; If “No,” the Vendor (Other Party) is not a Business Associate and a BAA is not required.***
 - a. For a definition of what constitutes PHI, refer to the following link: <http://portal.stanfordmed.org/depts/ComplianceDepartment/SHC%20Compliance%20%20Privacy%20Policy%20Manual/What%20Is%20PHI.pdf>
 - b. Members of a Stanford entity’s workforce include employees, volunteers, interns, and others whose conduct in the performance of work is directly under the control of a Stanford entity. Individuals can be members of a Stanford entity’s workforce even if they are paid by another party, as long as their work is managed and controlled by the Stanford entity. Temporary staffing resources are often a gray area. Stanford’s practice is to err on the strict side and seek BAAs with staffing agencies for HIPAA compliance and accountability.

2. ***Is the recipient of PHI a healthcare provider who is receiving PHI for treatment purposes only? If “Yes,” the provider is not a Business Associate and a BAA is not required. However, consider including the HIPAA Confidentiality provision in any contract with the Vendor (Other Party). If “No,” continue to Question 3.***
 - a. Examples of disclosures for patient treatment purposes include: disclosures to physicians, hospitals, clinics, radiology providers, pharmacies, and providers of medical or care related supplies such as pumps and durable medical equipment. NOTE: If the provider receiving PHI provides other services (i.e., in addition to patient treatment) to a Stanford entity, the provision of these other services may result in the provider being a HIPAA Business Associate.
 - b. Another frequent type of treatment-related disclosure involves the presence of medical device company personnel during procedures being performed with their company’s devices. In such cases, a HIPAA Confidentiality provision must be inserted in contracts that notifies the Vendor (Other Party) and/or the Vendor (Other Party) personnel of their obligation to comply with applicable Stanford policies, including Vendormate (a third-party vendor credentialing firm) registration.

3. ***Is the PHI being disclosed to a health insurance plan for payment purposes? If “Yes,” the health plan recipient is not a Business Associate and a BAA is not required. If “No,” continue to Question 4.***
 - a. Stanford entities may disclose PHI to insurance plans, including private and Medicare/Medicaid, in order to obtain payment for services. No business associate relationship is formed as both Stanford entity and the insurer are considered to be acting on behalf of the patient.
 - b. A Vendor (Other Party) would be considered a Business Associate if a PHI disclosure is made to a non-health insurance plan payment processor or other party retained to facilitate payment or other payment related services. In such cases, a Business Associate Addendum is required.

4. ***Is the PHI being disclosed to another Stanford entity that is part of the Stanford Affiliated Covered Entity (“ACE”)? If “Yes,” the recipient is not a Business Associate and a BAA is not required. If “No,” continue to Question 5.***
 - a. The ACE encompasses the Stanford University School of Medicine, certain Stanford University departments, Stanford Health Care, Lucile Salter Packard Children’s Hospital at Stanford, The Hospital Committee for the Livermore-Pleasanton Areas, University HealthCare Alliance, and Packard Children’s Health Alliance. More information regarding the ACE can be found at <https://privacy.stanford.edu/other-resources/covered-entity>.
5. ***Does the Vendor (Other Party) provide consulting, data aggregation, legal, actuarial, accounting, auditing, management, administrative, accreditation, or financial services to the Stanford entity? If “Yes,” the Vendor (Other Party) is a Business Associate and a BAA is required. If “No,” continue to Question 6.***
6. ***Does the Vendor (Other Party) access, store, or transmit PHI on a regular, routine, or ongoing basis (including, for example, cloud computing vendors; vendors that perform service, support, or maintenance on medical or other equipment that stores or processes PHI; e-prescribing gateways; health information organizations; or records storage vendors)? If “Yes,” the Vendor (Other Party) is a Business Associate and a BAA is required. If “No,” continue to 7.***
 - a. If the Vendor (Other Party) is engaged only in the transmission, and not the storage of PHI, regardless of whether the transmission is physical (e.g., couriers, UPS or FedEx) or electronic, the “conduit” exception applies and the Vendor (Other Party) is not a Business Associate. NOTE: The conduit exception is read narrowly and does not apply to a vendor that requires ongoing or recurring access to the PHI it transmits. For example, a teleconference service would be a Business Associate if it provides functionality for recording or archiving conference calls.
 - b. If exposure to PHI may occur on an infrequent or occasional basis while performing a service that does not require direct PHI access, such access is incidental in nature and a BAA is not required. In certain of these cases, it may be prudent to use the HIPAA Confidentiality clause in any contract with the Vendor (Other Party).
7. ***Does the Vendor (Other Party) create, receive, maintain, or transmit PHI for a function or activity that is regulated by HIPAA (such as healthcare operations or payment functions) including claims processing or administration; data analysis, processing or administration; or utilization review, quality assurance, patient safety activities, billing, benefit management, practice management, or repricing services? If “Yes,” the Vendor (Other Party) is a Business Associate and a BAA is required. If “No,” a BAA is not required.***

OTHER INSTANCES IN WHICH A BAA MAY NOT BE REQUIRED

In addition to the most commonly occurring situations summarized above, there are other instances in which a BAA may not be required for disclosure of PHI by a Stanford entity, including:

1. Disclosures to governmental agencies pursuant to official investigations (e.g., Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services Office for Civil Rights, U.S. Food and Drug Administration, Federal Bureau of Investigation).

2. Disclosures to FDA-regulated medical device manufacturers for adverse event reporting or for other purposes relating to the quality, safety, or effectiveness of an FDA-regulated device.
3. Research conducted pursuant to a Stanford institutional review board (IRB) approval and in which appropriate informed consent forms are obtained from the subjects of the research.