



QUESTIONS TO DETERMINE IF A CONTRACT REQUIRES A BUSINESS ASSOCIATE AGREEMENT (BAA) AND A QUALIFIED SERVICE ORGANIZATION AGREEMENT (QSOA)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FINANCE

SFN 626 (2-2025)

This form is to be used by HIPAA Covered Components to determine the need for a Business Associate Agreement and a Qualified Service Organization Agreement.

SECTION A - GENERAL INFORMATION FOR CONTRACTING

Division	Section/Program
Vendor Name	
Contract Number or Agreement Number (if applicable)	Service Dates
Provide a detailed description of the service(s) to be provided or functions to be performed:	
Will the Vendor use outsourced service providers for any of the following services: Third-party warehousing, internet hosting, healthcare claims processing, retirement plan administration, or loan services? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Will the Vendor have access to Department information systems or applications? <input type="checkbox"/> NO <input type="checkbox"/> YES. Yes. List the information systems or applications:	

SECTION B - BUSINESS ASSOCIATE INITIAL DETERMINATION

When the Department enters into a contract with a vendor, it must determine if the vendor is a Business Associate. If the vendor is a Business Associate, a Business Associate Agreement (BAA) must be executed in addition to the contract. It is the responsibility of the Department Division or Section to ensure that a valid BAA is executed. If the Division or Section needs assistance in completion of this form, they should consult with the HIPAA Privacy Officer or the Legal Division.

"Business Associate" means 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.

"Protected Health Information" (PHI) means individually identifiable health information, including demographic and genetic information created or received by a health care provider, health plan, or health care clearinghouse, that 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; and identifies the person or there is a reasonable basis to believe the information can be used to identify the person. PHI excludes:

- Any information about an individual that does not identify the individual, and with respect to which there is no reasonable basis to believe that the information can be used to identify the individual;
- Any information regarding an individual who has been deceased for more than 50 years; and
- Employment records held by the Department in its role as an employer.

"Vendor" means an outside person or entity that enters into a contract to provide a service to the Department Division or Section or to perform a certain function on behalf of the Department Division or Section.

1. Will the Department disclose PHI to the vendor or will the Department grant the vendor access to PHI?

- ☐ NO, STOP. This contract does not require a BAA. Proceed to Section C.
- ☐ YES. Proceed to the next question.

2. Certain categories of vendors who provide services to the Department and who receive PHI are always considered Business Associates. Is the vendor providing one of the services listed below to the Department, or performing one of the functions listed below on behalf of the Department?

Services:

- ☐ Legal
- ☐ Actuarial
- ☐ Accounting
- ☐ Consulting
- ☐ Data Aggregation
- ☐ Management
- ☐ Administrative
- ☐ Accreditation
- ☐ Financial

Functions:

- ☐ Claims processing or administration
- ☐ Data analysis, processing or administration
- ☐ Utilization review
- ☐ Quality assurance
- ☐ Billing
- ☐ Benefit Management
- ☐ Practice Management
- ☐ Repricing

☐ YES. This contract requires a BAA. Proceed to Section C. ☐ NO. Proceed to the next question.

3. Is the vendor (person or entity) a health care provider? If yes, will the Department disclose PHI to the health care provider “for treatment purposes only”?

- ☐ If the answer to both questions is YES, this contract does not require a BAA. Proceed to Section C.
- ☐ NO. Proceed to the next question.

4. Is the vendor a health plan? If yes, will the Department disclose PHI to the health plan for payment purposes? Example: Department discloses PHI to Medicaid, Blue Cross Blue Shield, or other private health plan to seek reimbursement for a service or treatment provided to an individual.

- ☐ If the answer to both questions is YES, this contract does not require a BAA. Proceed to Section C.
- ☐ If the answer to either question is NO, proceed to the next question.

5. Is the vendor acting as a mere conduit for the transmittal of PHI such as the U.S. Postal Service, Fed Ex, internet service provider or telecommunications company? If yes, will the vendor not have routine access to PHI other than infrequently or on a random basis?

- ☐ If the answer to both questions is YES, this contract does not require a BAA. Proceed to Section C.
- ☐ If the answer to either question is NO, proceed to the next question.

6. Will the vendor be considered a member of the Department's workforce? Workforce includes employees, contractors, volunteers, interns, students, and other persons whose conduct, in performance of work for the Department, is under the direct control of the Department, regardless of whether or not they are paid by the Department.

- ☐ YES. This contract does not require a BAA. Proceed to Section C.
- ☐ NO. Proceed to the next question.

7. Is the Department disclosing PHI to a researcher for research purposes?

- ☐ YES. This contract does not require a BAA. Proceed to Section C.
- ☐ NO. Proceed to the next question.

8. Is the Department disclosing PHI to a government agency pursuant to an official investigation? Examples: CMS, HHS, OCR and FDA?

- ☐ YES. This contract does not require a BAA. Proceed to Section C.
- ☐ NO. Proceed to the next question.

9. Is the Department disclosing PHI to a government agency for eligibility determination or enrollment in a government health plan that provides public benefits and is administered by another government agency?

- ☐ YES. This contract does not require a BAA. Proceed to Section C.
- ☐ NO. This contract requires a BAA. Proceed to Section C.

SECTION C - PART 2 SUBSTANCE USE DISORDER INFORMATION

Contact the HIPAA Privacy Officer or the Legal Division if you need assistance completing this section.

“Part 2” means 42 CFR Part 2, the federal regulations governing the Confidentiality of Substance Use Disorder Patient Records.

“Substance Use Disorder” means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. It does not include tobacco or caffeine use.

A “Part 2 Program” means any individual or entity that holds themselves out as providing, and provides substance use disorder diagnosis, treatment or referral to treatment. It includes units within a general medical facility that holds themselves out as providing diagnosis, treatment, or referral to treatment and receives federal assistance in any form including financial assistance which does not directly pay for the substance use disorder diagnosis, treatment or refer for treatment.

“Part 2 Patient Identifying Information” means any information, regardless of format, that identifies an individual as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person, obtained by a Part 2 Program.

“Lawful holder” means a person who is bound by the Part 2 Regulations because they have received Part 2 Patient Identifying Information/records as the result of a Part 2 compliant authorization (along with a notice of prohibition on re-disclosure), or as a result of one of the limited exceptions to the authorization requirement in the Part 2 Regulations. Whether an individual or entity is a “lawful holder” is fact-specific.

1. Will the information disclosed by the Department Division, Section, or Program include “Part 2 Patient Identifying Information”? Note, this includes “Part 2 Patient Identifying Information” the Division, Section, or Program has received from third parties.

- ☐ NO, STOP. Part 2 does not apply to this contract.
☐ YES. Proceed to the next question.

2. Is the Department Division, Section, or Program a “Part 2 Program” or a “Lawful Holder” of Part 2 Patient Identifying Information?

- ☐ NO, STOP. Part 2 does not apply to this contract.
☐ Part 2 Program. Proceed to Section D.
☐ Lawful Holder of Part 2 Patient Identifying Information. Proceed to Section D.

SECTION D

The section will assist in determining if a Qualified Service Organization Agreement (QSOA), Lawful Holder Contract Provisions or Patient Authorization is required for the disclosure of Part 2 Patient Identifying Information to the Vendor.

1. Will the vendor provide any of the services listed below to assist the Department Division, Section, or Program in “payment” or “health care operations” functions?

- ☐ NO. Proceed to the next question.
☐ YES. Check all that apply and proceed to the next question.
- ☐ Accounting
 - ☐ Bill Collecting
 - ☐ Data Processing
 - ☐ Dosage Preparation
 - ☐ Laboratory Analysis
 - ☐ Legal Services
 - ☐ Medical Staffing Services
 - ☐ Population Health Management
 - ☐ Professional Services
 - ☐ Services to prevent/treat child abuse or neglect, including training on nutrition and childcare and individual and group therapy

2. Will the service(s) provided by the vendor include a "treatment component" listed below? <input type="checkbox"/> NO. Proceed to next question. <input type="checkbox"/> YES. Check all that apply and proceed to the next question. <div><input type="checkbox"/> Care Coordination <input type="checkbox"/> Case Management <input type="checkbox"/> Medical Management Services</div>
3. Is the vendor a Part 2 Program? <input type="checkbox"/> NO <input type="checkbox"/> YES

Form Completed by (Name of Division, Section, or Program Representative)	Date
Senior Management Signature (Required)	Date

HIPAA Privacy Officer/Legal Division Review

1. Does contract require BAA? <input type="checkbox"/> NO <input type="checkbox"/> YES	
2. Does Part 2 apply to contract? <input type="checkbox"/> NO <input type="checkbox"/> YES <div><input type="checkbox"/> QSOA Required <input type="checkbox"/> Lawful Holder Contract Provisions Required <input type="checkbox"/> Patient Written Authorization Required</div>	
<div>Comments</div>	
HIPAA Privacy Officer/Legal Division Signature (Required)	Date