Decision Tree: When is a Business Associate Agreement (BAA) Required?

Saint Louis University, a Covered Entity under HIPAA, is required to sign Business Associate Agreements with certain organizations and individuals to whom they share Protected Health Information (PHI). Business Associates are outside organizations or individuals who perform some function or service for Saint Louis University that requires them to have access to our patients’ information.

The HIPAA rule on Business Associates has many complicated details and exceptions, as well as a number of ambiguous definitions and interpretations. This Decision Tree guidance is provided to assist in the process of identifying when a Business Associate Agreement (BAA) is necessary.

Before you use this decision tree you must make an initial decision:“Is Protected Health Information (PHI) being disclosed to an outside entity?”

You must understand what constitutes PHI is to make this determination. Protected Health Information (PHI) can be broadly defined as meaning:

Any oral or recorded information relating to past, present, or future physical or mental health of an individual, the provision of health care to the individual, or the payment for health care and that also contains information which makes it possible to identify the individual.

If you decide that PHI is actually being disclosed from your site, then move on to Decision Point #1.

DECISION Point # 1 –

Is PHI being disclosed to another healthcare provider for treatment purposes only?

Frequent disclosures made to outside entities are for services or products used solely to treat a patient or group of patients. When the disclosure of PHI is to outside entities for treatment only purposes, then a Business Associate Agreement is not required.
The following are common examples of disclosures of PHI that do not require Business Associate Agreements due to the “treatment only” provision.

1. Providers of direct health care services for patients such as: attending physicians, dentists, podiatrists, psychologists, hospitals, clinics, dialysis facilities, laboratories, radiology providers, pharmacy distributors, and optometrists.
2. Providers of medical or care related supplies including such as pumps and other durable medical equipment.
3. Ambulance and other medical transportation systems that request patient billing information in order to transport.

SPECIAL NOTE: There are instances where health care professionals provide treatment directly to the patient on their behalf, yet also perform other services on the Facility’s behalf and would be considered a Business Associate. For example, a pharmacy may not only distribute medications but may also provide pharmacy consultant services. Likewise, a medical supply company may not only supply the wound care product but may also provide wound therapy consultation.

These situations highlight the importance of examining all dimensions and functions of the relationship between the outside entity and the facility before making a quick decision. You can not assume exemption simply based on job title or function.

DECISION Point # 2 –

Is PHI being disclosed to an insurance plan for Payment Purposes?

A facility may disclose PHI to an insurance plan, including private insurance, Medicaid and Medicare, for patients, in order to assure payment for those services. Neither the health plan nor the facility is considered business associates of each other since both are considered to act individually on behalf of the patient.

The following examples illustrate payment for services that do not require a Business Associate Agreement.

1. Patient information sent to CMS for categorization and payment.
2. Rehabilitation progress notes sent to a managed care company to verify treatment sessions.
3. Benefit and eligibility verification on the part of the facility.

SPECIAL NOTE: If documents containing PHI, such as a remittance advice or Explanation of Benefits (EOB), are given to a bank in order to consolidate payments to the facility, then a Business Associate Agreement would be required. In this situation they are performing a function on behalf of the facility and not for the individual patient.

Psychotherapy notes are an exception that can not be released for payment without patient authorization.
DECISION Point # 3 –

Is PHI being disclosed for official investigation or proceeding?

There are a number of exemptions to the Business Associate Agreement requirement if the PHI that is disclosed is required for:

- Activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections and licensure; disciplinary actions; civil, administrative, or criminal proceedings or actions.
- Appropriate governmental oversight of health care systems, government benefit programs, or government regulatory programs.

The following examples illustrate disclosure of PHI to oversight, regulatory and legal agencies that do not require a Business Associate Agreement.

1. Reporting of state-required reportable diseases to the Department of Public Health. Some examples of diseases that may require notification are:
   - AIDS • Malaria
   - Anthrax • Plague
   - Botulism • Rubella
   - Diphtheria • Streptococcal disease, invasive, group A
   - Legionellosis • Syphilis
   - Malaria • Tuberculosis

2. A CMS survey (e.g. the facility’s annual health department survey) where PHI is reviewed by a surveyor
3. A Department of Health/DHHS/State agency visit which was prompted due to staff/visitor/patient complaint
4. Death reporting to the state
5. Law enforcement officials investigating abuse of a patient
6. OSHA reporting
7. To a social services or protective agency authorized to receive reports of abuse, neglect, or domestic violence (except child abuse);
8. For judicial or administrative proceedings where required by order of a court or in response to a subpoena or discovery request.

Decide first if the oversight agency has legal authority to receive the PHI. If so, then a Business Associate agreement is not required.
DECISION Point # 4 –

Is PHI being disclosed or accessed on behalf of the facility?

The term “on behalf of the facility” means a function or service that is necessary for a facility but the organization chooses to outsource to another entity. These situations will require a Business Associate Agreement when the exchange of PHI is necessary for the function or service to be performed.

The function or service is provided for the direct benefit of the facility and typically involves activities that support, and/or enhance the facility’s ability to provide direct care to patients. Specific examples mentioned in the rule include:

- Claims processing & administrations • Legal services
- Data analysis, processing, administration • Actuarial services
- Utilization review • Consulting services
- Quality assurance • Data aggregation
- Billing • Management
- Benefit management • Administrative
- Practice management • Accreditation
- Financial Services

The following are examples of services provided on the covered entity’s behalf that would require a Business Associate Agreement.

1. Agencies providing accreditation services such as JCAHO
2. Medical Directors acting in their administrative role on behalf of a facility.
3. Software vendors having access to PHI during the course of business.
4. Computer hardware service companies having access to PHI in electronic form.
5. Companies providing billing services that have access to PHI in the course of receiving electronic transactions to submit to payers for reimbursement.
6. Non-Facility Consultants such as: HIM/Medical Record, Dietary, Infection Control
7. Payers performing functions that are in addition to, and not directly related to the provision of insurance.
8. Attorneys who are representing the facility in a legal dispute.
9. Shredding services that have direct access to PHI in order to do their job.

SPECIAL NOTE: In the vast majority of cases where PHI is exchanged with an outside entity on the facility’s behalf, the facility is responsible to pay the entity for the service or product the outside entity provides. This is in contrast to the “treatment only” situation where the patient themselves or their insurer are typically financially responsible.
DECISION Point # 5 –

Is the Entity that is receiving the PHI considered part of your workforce?

Workforce is defined as employees, volunteers, students, trainees, and other persons whose conduct, in the performance of work, is under the direct control of the covered entity, **whether or not they are paid by the covered entity**.

The following examples are typical instances of people who are not employed by us but are defined by HIPAA as "workforce", and would not need a Business Associate Agreement.

1. A volunteer working in HIM/Medical records filing loose reports of discharged patients – The volunteer’s conduct is under the control of the covered entity.
2. A student performing a clinical internship at the facility - Although their internship defines the scope of their activities, while they are in the facility, the performance of these activities is supervised/overseen by a member of the CE’s workforce.

**SPECIAL NOTE:**

*There are some instances when a facility has the choice of whether to consider a contractor as workforce versus Business Associate. For example, temporary staffing resources in the billing office who participate in management meetings and who spend most of their time at the facility could be considered either workforce or business associate. The presumption is made that if there is not a Business Associate Agreement in place then it is assumed that the resource is part of your workforce. The decision-maker needs to weigh the pros and cons of such a decision from an operational and legal standpoint.*

DECISION Point # 6 –

Is PHI being disclosed preparatory to research purposes?

The Privacy Rule permits covered entities to use and disclose PHI for research purposes with individual patient authorization and without authorization under limited circumstances, although research protocols will require Institutional Review Board (IRB) approval.

During the preparatory to research process, a researcher who is an employee or member of the covered entity’s workforce can use protected health information to contact prospective research subjects. The preparatory research provision would allow such a researcher to identify prospective research participants for purposes of seeking their authorization to use or disclose PHI for a research study.

A covered entity could also contract a Business Associate, who may assist in contacting individuals on behalf of the entity to obtain their Authorization. In this situation a Business Associate Agreement is required.
SPECIAL NOTE: A researcher who is not part of the covered entity may not use the preparatory to research provision to contact prospective research subjects.

The outside researcher could obtain contact information through a partial waiver of individual authorization by the IRB to permit disclosure of PHI as necessary for the research to be able to contact and recruit individuals into the study.

Common Business Associates

The following list contains entities that are typically Business Associates by the nature of their relationship with the facility. This list does not include all possible Business Associates and assume all services are provided by persons not considered workforce. You should routinely analyze these and all future contracts according to the decision tree to assure compliance and avoid the possibility of signing Business Associate Agreements when they are not required.

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<thead>
<tr>
<th>Attorney (external)</th>
<th>Medical Director (external)</th>
<th>Medical Coding Service</th>
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<tbody>
<tr>
<td>Mental Health Consultant</td>
<td>Medical Record Consultant</td>
<td>Ancillary Charge System</td>
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<tr>
<td>CNA Instructors</td>
<td>Pharmacy Consultant</td>
<td></td>
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<tr>
<td>Computer Consultant</td>
<td>Psychiatry Consultant</td>
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<tr>
<td>Contracted Billing</td>
<td>Record Destruction Service</td>
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<tr>
<td>Infection Control Consultant</td>
<td>Transcription Services</td>
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<tr>
<td>JCAHO</td>
<td>Record Copying Service</td>
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Temporary/contracted employees such as nursing or therapy may be considered either as workforce or business associate.