

BUSINESS ASSOCIATE AGREEMENTS

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook is issued to provide policy and procedures for the establishment and management of Business Associate Agreements (BAA) between VA medical facilities and designated Business Associates.
- 2. SUMMARY OF MAJOR CHANGES:** This revision of VHA Handbook 1605.05:
 - a. Incorporates updates pursuant to changes to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, Breach Notification and Enforcement Rules as promulgated by the Department of Health and Human Services (HHS), Office for Civil Rights (OCR).
 - b. Updates the Business Associate Agreement template.
 - c. Updates the Business Associate Decision Tree.
 - d. Incorporates new Department of Veterans Affairs (VA) and VHA guidance.
- 3. RELATED ISSUES:** VA Directive 6066, VA Handbook 6500.6, and VHA Directive 1605.
- 4. RESPONSIBLE OFFICE:** The VHA Office of Informatics and Analytics (10P2) is primarily responsible in coordination with VHA National Data Systems (NDS), Health Information Access (HIA) Office for the contents of this Handbook. Questions may be referred to 615-564-0687.
- 5. RESCISSIONS:** VHA Handbook 1605.05, dated February 27, 2013, is rescinded.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of July 2019.

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BUSINESS ASSOCIATE AGREEMENTS

1. PURPOSE: This Veterans Health Administration (VHA) Handbook states the responsibilities and procedures for establishing and managing Business Associate Agreements (BAA) between VA medical facilities and Business Associates. **NOTE:** When applicable, the same guidance applies to Veterans Integrated Service Networks (VISN) and VHA Program Offices.

2. BACKGROUND:

a. Under the Health Insurance Portability and Accountability (HIPAA) Act of 1996 Privacy Rule, promulgated by the U.S. Department of Health and Human Services (HHS), a Covered Entity must enter into a BAA with any person or organization that requires access to protected health information (PHI) in order to perform certain health care operations activities or functions on behalf of the Covered Entity, or to provide one or more of the services specified in the Rule to or for the Covered Entity. A BAA is required even if no underlying contract exists between the Covered Entity and the Business Associate.

b. VHA is the only administration of the Department of Veterans Affairs' (VA) that is a Covered Entity under the HIPAA Privacy Rule. HIPAA regulations require VHA to execute HIPAA-compliant BAAs with appropriate parties that create, receive, maintain, or transmit VHA PHI to perform activities, functions or services for VHA. BAAs obligate VHA Business Associates to provide the same protections and safeguards and agree to the same disclosure restrictions to PHI that is required of VHA under the Privacy Rule.

c. The Health Information Technology for Economic and Clinical Health (HITECH) Act's Final Omnibus Rule applies the security and privacy requirements of the HIPAA Rules to Business Associates, and their subcontractors, in the same manner that such requirements apply to Covered Entities, and requires that these provisions be incorporated into the BAAs. Subcontractors of Business Associates are now considered to be Business Associates with the same liabilities.

d. VHA BAA operational requirements are the responsibility of the VHA National Data Systems (NDS), VHA Health Information Access (HIA) Office. The VHA NDS/HIA Office negotiates and engages in national BAAs for VHA. Instead of requiring separate BAAs for each VA medical facility conducting business with the same Business Associate, VHA executes a single national agreement. The HHS Office for Civil Rights (OCR) has approved the national BAA concept. The VHA NDS/HIA Office also offers BAA consultative services throughout VA. The policy requirements of Business Associate management are the responsibility of the VHA Office of Informatics and Analytics, Information Access and Privacy (10P2C1).

3. DEFINITIONS:

NOTE: Terms defined in statutes, regulations, and this handbook, are intended to have the same meaning. The definitions in this handbook are meant to be easy to understand and maintain the legal meanings of the terms.

a. **Access.** Access is the viewing, inspecting, or obtaining a copy of PHI electronically, on paper or through another medium.

b. **Breach.** A breach is an unauthorized acquisition, access, use, or disclosure of PHI in a manner not permitted under the HIPAA Privacy Rule which compromises the security or privacy of the PHI by posing a significant risk of financial, reputational, or other harm to the individual.

c. **Business Associate.** A Business Associate is an entity, including an individual (other than a member of VA's workforce), company, organization or another covered entity, that performs or assists in the performance of a function or activity on behalf of VHA that involves the creating, receiving, maintaining or transmitting of PHI, or that provides to or for VHA certain services as specified in the Privacy Rule that involve the disclosure of PHI by VHA. The term "Business Associate" also includes a subcontractor of a Business Associate that creates, receives, maintains, or transmits protected health information on behalf of the Business Associate.

d. **Covered Entity.** A Covered Entity is a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Privacy Rule. VHA is both a health plan and a health care provider.

e. **Disclosure.** Disclosure is the release of, transfer of, provision of access to, or divulging in any manner of, information outside VHA. ***NOTE: The only exception to this definition is when the term is used in the phrase "accounting of disclosures."***

f. **Health Care Operations.** Health Care Operations are certain activities as related to VHA's function as a health care provider including: conducting quality assurance and improvement activities; population based activities relating to health care improvements or health care cost reduction, protocol development, or case management; review of a health care professional's competence or qualifications, practitioner performance, health plan performance, training programs, and certification, licensing, or credentialing activities; conducting medical reviews, legal services, and auditing functions; business planning and development; business management and general administrative activities including management, customer service, and resolution of internal grievances.

g. **Individually-identifiable Health Information.** Individually-identifiable Health Information (IIHI) is a subset of health information, including demographic information collected from an individual that:

- (1) Is created or received by a health care provider, health plan, or health care clearinghouse;
- (2) 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 to an individual; and
- (3) Identifies the individual or provides a reasonable basis to believe it can be used to identify the individual.

h. **Payment.** Payment is any activity undertaken by a health care provider or a health plan to obtain or provide reimbursement for the provision of health care, including pre-certification and utilization review.

i. **Protected Health Information.** Protected Health Information (PHI) is individually-identifiable health information transmitted or maintained by a Covered Entity in any form or medium. *NOTE: PHI excludes employment records held by a Covered Entity in its role as an employer or health information belonging to an individual deceased more than 50 years.*

j. **Security Incident.** An event that has, or could have, resulted in the access, use, disclosure, modification, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures.

k. **Treatment.** Treatment is the provision, coordination, or management of health care or related services by one or more health care provider. This includes the coordination of health care by a health care provider with a third-party, consultation between providers regarding a patient, or the referral of a patient from one health care provider to another.

l. **Use.** Use is the sharing, employment, application, utilization, examination, or analysis of IHI within VHA.

4. CATEGORIES OF BUSINESS ASSOCIATE AGREEMENTS:

a. All VA medical facilities providing PHI to another person or entity that is acting as a Business Associate, as part of a BAA, do so only under the authority of either a national or local BAA. *NOTE: See Appendix A to determine what entities qualify as Business Associates.*

b. **Local Business Associate Agreements.** A local Business Associate Agreements (BAA) is negotiated and executed between a single VA medical facility and a single Business Associate. If the Business Associate provides services or activities meeting the Business Associate definition for two or more facilities, then a national BAA must be negotiated with that Business Associate.

c. **National Business Associate Agreements.** A national Business Associate Agreements (BAA) is negotiated and executed by the NDS/HIA Office and represents the agreements between two or more VA medical facilities (to include services contracted by a VISN, Regional or VHA Program Office contracting office) and a Business Associate. No other BAA may be executed when a national BAA is in place without prior approval by the NDS/HIA Office. *NOTE: The National BAA will be executed separately as a stand-alone document referencing the underlying contract or agreement. This allows BAA language to be used in multiple contracts and agreements and permits review of BAAs without re-negotiation of the terms of any underlying contracts or agreements.*

5. RECOGNIZING THE NEED FOR A BUSINESS ASSOCIATE AGREEMENT: The HIPAA Privacy Rule requires VHA to execute compliant BAAs with persons or entities that create, receive, maintain, or transmit VHA PHI in order to perform an activity, function or service to, for or on behalf of VHA. The Privacy Rule also requires Business Associates to obtain assurances that their subcontractors will comply with HIPAA requirements to the same

degree as the Business Associates. VA Administrations or Staff Offices that are Business Associates of VHA must obtain these assurances in writing from subcontractors that create, receive, maintain or transmit PHI in the performance of services to the Business Associate and VHA. VA Administrations or Staff Offices that are Business Associates of VHA must follow guidance in VA Directive 6066, Protected Health Information, to ensure compliance with their relationship with subcontractors.

a. The Chief Program Officer, VISN Director, VA Medical Facility Director, Contracting Officer (CO), Privacy Officer, Information Security Officer (ISO), and Contracting Officer's Representative (COR) must work together to identify entities that are Business Associates under HIPAA. Prior to disclosing any PHI to a Business Associate, a valid BAA must be executed in accordance with this policy.

b. Business Associates providing services as described in paragraph 4b may be eligible for a national BAA; such Business Associates need to be identified to the NDS/HIA Office, which will administer all national agreements.

c. Because mandatory security requirements must be included in contracts where VA must disclose PHI or sensitive VA information or even VA information, contracts must be the primary acquisition vehicle for acquiring Business Associate services. Contract solicitations must be managed according to VA Handbook 6500.6 to ensure BAAs are incorporated into the contracting process when required. *NOTE: Contracts are not the only instruments that can give rise to a HIPAA Business Associate relationship. Purchase Orders, modifications, purchase card orders and other underlying agreements must be evaluated for Business Associate implications and a BAA must be entered into regardless of the purchase instrument used in situations where VHA PHI must be disclosed in order for certain services/functions to be carried out on behalf of VHA.*

6. RESPONSIBILITIES FOR COMPLETING A BUSINESS ASSOCIATE

AGREEMENT: The VHA Privacy Office, VHA NDS/HIA Office, VA Facility Director, CO, Privacy Officer, ISO, and COR work together to ensure BAAs are enacted for all Business Associates.

a. **VHA Privacy Office.** The VHA Privacy Office provides guidance on VHA policies and procedures for complying with the HIPAA Privacy Rule and the HITECH Act regarding the Business Associate provisions.

b. **NDS/HIA Office.** The NDS/HIA Office is responsible for:

- (1) Managing and monitoring the BAA business processes for VHA;
- (2) Negotiating and signing national BAAs on behalf of VHA;
- (3) Providing support to field personnel regarding local BAAs;
- (4) Establishing guidance for all operational aspects of BAA management;

(5) Coordinating a Business Associate assessment process with the Information Access and Privacy, Privacy Compliance Assurance Office; and,

(6) Monitoring the Daily Incident Reports published by the VA Risk Management and Incident Response, Incident Resolution Team for any incidents involving Business Associates.

c. **Chief Program Officer, Veterans Integrated Service Network Director or VA Medical Facility Director.** The Chief Program Officer, Veteran Integrated Service Network (VISN) Director, or VA Medical Facility Director is responsible for identifying Business Associates, verifying BAA status, and ensuring BAAs have been executed appropriately and in accordance with VHA policy, to include designating signature authority for local BAAs.

d. **Contracting Officer or Responsible Staff.** *NOTE: If a relationship with any person or entity constitutes a Business Associate relationship, but is not bound by a formal contract, the CO or whoever engaged the associate (responsible staff) is responsible for establishing and maintaining a BAA.* The CO, or responsible staff, is responsible for ensuring:

(1) Compliance with the mandates of the VHA Procurement Manual, Volume 2.

(2) In collaboration with the VHA Facility Privacy Officer and ISO, that all persons or entities meeting the definition of a Business Associate have been identified.

(3) In collaboration with the VHA Facility Privacy Officer, that BAAs have been, or are in the process of being executed, for all contracts (except as noted in App. B) where the contractor meets the definition of a Business Associate. *NOTE: A list of signed national level BAAs is maintained on the VHA NDS/HIA Office Web site at:*

<http://vaww.vhadatportal.med.va.gov/DataAccess/BusinessAssociateAgreements.aspx>. This is an internal VA Web site and is not available to the public.

(4) That any BAA being negotiated is verified as not duplicating pre-existing agreements. If it appears that a national BAA might apply to the services being contemplated, the CO or responsible staff must review the first paragraph of the national BAA to determine if it covers those services. If so, the national BAA must be incorporated into local procurement paperwork. If a national BAA does not apply, a local BAA must be executed or in development prior to disclosing PHI. *NOTE: The sample BAA provided in Appendix B or an updated equivalent must be used as a template.*

(5) That any Business Associate subject to a national BAA is identified to the VHA NDS/HIA Office.

(6) That copies of local BAAs, VISN, and regional level BAAs executed for a single facility, are maintained at the appropriate VHA facility, and that the VHA Facility Privacy Officer has access to these agreements in order to monitor their performance against the terms of the BAA.

e. **VHA Facility Privacy Officer.** The VHA Facility Privacy Officer is responsible for ensuring:

(1) In collaboration with the ISO and CO, that all entities meeting the definition of Business Associate have been identified. *NOTE: Appendix A can be utilized to determine if an entity is a Business Associate.*

(2) In collaboration with the CO, that all Business Associates have executed a BAA prior to disclosing PHI. *NOTE: The BAA provided in Appendix B can be modified, as appropriate, to meet this requirement; however any modifications that may alter the intent of the original language to the standard BAA template in Appendix B must be reviewed and approved by the appropriate regional counsel, by the VA Office of General Counsel, or by VHA NDS/HIA. See Appendix A for common exemptions.*

(3) Compliance with VHA Facility Privacy Officer requirements pertaining to Business Associate Compliance Monitoring activities as defined in VHA Handbook 1605.03.

(4) In collaboration with the CO, any local BAA is accounted for and inventoried when required.

f. **Information Security Officer.** The ISO is responsible for ensuring:

(1) In collaboration with the VHA Facility Privacy Officer and CO, that all entities meeting the definition of Business Associate have been identified. *NOTE: Appendix A can be utilized to determine if an entity is a Business Associate.*

(2) Applicable security requirements are included in statements of work, and in contracts and agreements for hardware, software, information technology, and related services by contractors that meet the definition of a Business Associate.

(3) Security requirements and specifications are properly implemented before any system containing PHI goes into operation and throughout the life cycle of the system.

g. **Contracting Officer's Representative.** The COR is responsible for ensuring that Contracts have separate, fully executed, and current BAAs when the contractor meets the definition of a Business Associate. *NOTE: The COR is a designated workforce member who provides technical direction within the general scope of a contract, assists the CO in preparing the acquisition plans and reports performance issues to the CO, among other duties.*

h. **VA Administrations or Staff Offices.** VA Administrations or staff offices that are Business Associates of VHA must follow guidance in VA Directive 6066, Protected Health Information, to ensure compliance with their relationship with Subcontractors.

7. BUSINESS ASSOCIATE AGREEMENT MAINTENANCE AND RENEWAL:

a. BAAs must be kept updated and documentation of Agreements must be maintained as long as the Agreements are in place. To this end, facilities must use the current BAA templates or other resources made available by the VHA NDS/HIA Office. Copies of local BAAs are to be maintained at the VISN or VA medical facility that signed the BAA. For local BAAs signed at the VISN or regional level, a copy must be provided to the local facilities receiving services from the Business Associate. All BAAs are to be reviewed by responsible staff every 2 years from the effective date to determine if underlying agreements for the same services still exist and whether changes need to be made to the BAA. Executed BAAs do not expire as long as an underlying agreement for the same services is in place.

b. The CO or responsible staff must monitor BAAs for patterns of activities and any practices by the Business Associate that may constitute a material breach or violation of the Business Associate's compliance obligations. Any such breach or violation must be reported to the VHA Facility Privacy Officer. The Business Associate must mitigate any harmful effects of a breach and attempt to cure the breach. If no cure is possible, the VA medical facility must terminate the BAA.

c. The CO or responsible staff member(s) must report any potential security incident or breach of PHI that involves a BA to their VHA Facility Privacy Officer or ISO, who will enter the incident or breach into the VA National Security Operation Center (VA NSOC) Remedy System, if appropriate.

d. Per the agreement, Business Associates must follow the mandates of VA, VHA, or Federal regulations as annotated in the templated language in Appendix B.

8. BUSINESS ASSOCIATE ASSESSMENTS:

a. NDS/HIA must establish and manage the operational relationship with all national Business Associates and must provide Information Access and Privacy, Privacy Compliance Assurance Office (PCA) with the names of national Business Associates to be assessed for compliance with the terms of the national BAA. PCA must maintain and implement an assessment program to evaluate the national Business Associate's compliance with the provisions of the BAA based on specifications defined by NDS/HIA and the VHA Privacy Office.

b. NDS/HIA and PCA must work in coordination to complete an annual Business Associate selection process based on a risk assessment using the Business Associate's profile information, previous assessment data or other known risks, incidents or breaches.

c. NDS/HIA must provide a final list of assessment candidates to PCA no later than the last day of the third quarter of each fiscal year in order for PCA to administer the compliance-monitoring program.

d. PCA, in conjunction with the VHA Health Care Security Requirements Office (HCSR), must conduct onsite assessments of Business Associates.

e. Reports of assessment findings, emergent situations and remediation actions need to be coordinated between NDS/HIA, PCA and the HCSR.

f. Business Associate self-assessments must be utilized as an alternative method of Business Associate compliance posture when onsite assessments are not feasible or timely and this process must be administered by PCA.

g. VA medical facilities must conduct assessments of local Business Associate relationships in accordance with VHA Handbook 1605.03, but are prohibited from conducting assessments of national Business Associates. Incidents or issues involving national Business Associates must be reported to NDS/HIA.

h. Prior written approval of the Director of the Medicare Analysis Center (MAC) must be obtained before VA Centers for Medicare & Medicaid Services (CMS) data or CMS Data files can be provided to a Business Associate. If VHA must provide VA-CMS Data or CMS Data files to a Business Associate in order for it to complete the Business Associate function(s), the Business Associate needs to be assessed by the PCA Office prior to receiving VA-CMS data or CMS Data files from VHA.

9. REFERENCES:

- a. Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191.
- b. Health Information Technology for Economic and Clinical Health (HITECH) Act, Public Law 111-5, Div. A §§ 13001 et seq.
- c. HIPAA Privacy, Breach Notification and Security Rules, 45 C.F.R. parts 160 and 164.
- d. VA Directive 6066, Protected Health Information.
- e. VA Handbook 6500.6, Contract Security.
- f. VHA Directive 1605, VHA Privacy Program.
- h. VHA Handbook 1605.1, Privacy and Release of Information.
- i. VHA Handbook 1605.03, Privacy Compliance Assurance Program and Privacy Compliance Monitoring.
- j. VHA Procurement Manual, Volume 2.

DECISION TREE FOR BUSINESS ASSOCIATE AGREEMENTS

NOTE: This Decision Tree is meant to be a general guide for determining the need for a Business Associate Agreement (BAA). Relationships not addressed in this Decision Tree should be referred to the VHA NDS/HIA Office for evaluation.

1. START

a. **Does the person or entity provide a service, function, or activity to the Veterans Health Administration (VHA) or on behalf of VHA?** *NOTE: See paragraph 4a. of this Appendix for examples of a Business Associate service, function, or activity.*

YES. KEEP GOING! This arrangement might require a BAA.

NO. STOP! This arrangement does not require a BAA.

b. **Does the person or entity create, receive, maintain or transmit VHA Protected Health Information (PHI) to perform the service, function, or activity?**

YES. KEEP GOING! This arrangement might require a BAA. Proceed to the following exemption questions.

NO. STOP! This arrangement does not require a BAA.

2. EXCLUSION AND EXEMPTION QUESTIONS

NOTE: This list is not all-inclusive; please check this Web site for a Department of Health and Human Services, Office of Civil Rights HHS/OCR list of exemptions:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/businessassociates.html>

a. **Workforce Exclusion: Is the person or entity a member of the VHA workforce, as “workforce” is defined in 45 CFR 160.103?** *NOTE: The VHA workforce consists of those with VA appointments (i.e., government employees, residents, students, volunteers, and Without Compensation employees).*

YES. STOP! This is not a Business Associate relationship and does not require a BAA.

NO. KEEP GOING! You must answer the following exclusion and exemption questions.

b. **Treatment Exemption: Is the person or entity a health care provider as defined under 42 U.S. C. 1395x(s) and 1395x(u)? and is the PHI being disclosed and/or used for treatment of an individual?** *NOTE: See Section 4b. of this Appendix for examples of a health care provider.*

If the answer to both questions is “YES,” STOP! This arrangement does not require a BAA.

If the answer to either question is “NO,” proceed with the following exemption questions.

NOTE: Read paragraph 3i of this Handbook for the definition of “treatment.”

c. Research Exclusion: Does the service, function, or activity meet the definition of research as defined in VA’s regulations implementing the Common Rule (section 16.102(d) of Title 38 Code of Federal Regulations (CFR)), or VHA Handbook 1200.05?

YES. STOP! This arrangement does not require a BAA. *NOTE: Although a BAA is not required, other legal requirements must be met to disclose PHI for research purposes (see VHA Handbook 1605.1, for details on disclosing information for research).*

NO. KEEP GOING! You must answer the following exclusion and exemption questions.

d. Health Plan-to-Health Care Provider Exclusion: Is the PHI being disclosed and/or used in VHA’s role as a health plan to pay for services to a health care provider?

YES. STOP! If the answer is “yes,” then this arrangement does not require a BAA.

NO. KEEP GOING! If the answer is “no,” proceed with the following exclusion and exemption questions.

e. Government Reporting Purposes Exclusion: Is the person or entity a government agency to whom you are providing PHI for legally-mandated reporting purposes?

YES. STOP! If the answer is “yes,” then this arrangement does not require a BAA. *NOTE: Although a BAA is not required, other legal requirements must be met to disclose PHI (see VHA Handbook 1605.1 for details on disclosing information in these situations.)*

NO. KEEP GOING! If the answer is “no,” proceed to “Final Steps.”

3. FINAL STEPS

If it has been determined that the arrangement is not exempt or excluded from the BAA requirements, negotiate, and execute a HIPAA compliant BAA utilizing the latest template.

4. EXAMPLES

a. Examples of Business Associate Functions, Activities, and Services Include, but are not limited to:

- (1) Accounting;
- (2) Accreditation;
- (3) Actuarial;
- (4) Administrative;

- (5) Benefit management;
- (6) Billing;
- (7) Claims processing or administration;
- (8) Consulting;
- (9) Data aggregation;
- (10) Data analysis, processing, or administration;
- (11) Financial;

(12) Legal; **NOTE:** *VHA has a national-level BAA with VA Office of General Counsel; Individual facilities should not sign a separate BAA with Regional Counsel.*

- (13) Management;
- (14) Medical equipment maintenance;
- (15) Practice management;
- (16) Quality assurance;
- (17) Re-pricing;
- (18) Utilization review; and
- (19) Other health care operations not specifically tied to treatment, research, and/or payment.

NOTE: *Numerous national BAAs have been signed for the preceding services, some of which cover Business Associate services provided to VHA by VA offices (for instance, the national BAA between VHA and OGC noted above). Local agreements are not required with Business Associates who have signed national level BAAs.*

b. Examples of Health Care Providers Include, but are not limited to:

- (1) Dentists;
- (2) Durable medical equipment (DME) suppliers;
- (3) Hospices;
- (4) Hospitals;
- (5) Home health agencies;
- (6) Nursing homes;

- (7) Pharmacies;
- (8) Physicians and/or group practices; and
- (9) Entities providing services pursuant to a health care provider's prescription.

July 22, 2014

VHA HANDBOOK 1605.05
APPENDIX B

**BUSINESS ASSOCIATE AGREEMENT BETWEEN THE DEPARTMENT OF
VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION AND
COMPANY/ORGANIZATION**

The Sample Business Associate Agreement (VHA BAA Template) reflects language for a local Business Associate Agreement; slightly edited versions will be used for National BAAs and agreements with accreditation agencies, can be found at Web site.

<http://vaww.vhadatportal.med.va.gov/DataAccess/BusinessAssociateAgreements.aspx>.

NOTE: This is an internal VA Web site and is not available to the public.

BUSINESS ASSOCIATE AGREEMENT PROCESS FLOW

