

# Business Associate Agreement

(Revised February 26, 2026)

## Definitions

### Catch-all definition:

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

### Specific definitions:

- a) Business Associate. "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean BetterDiagnostics, Inc.
- b) Covered Entity. "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean
- c) HIPAA Rules. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.
- d) Part 2 Information. "Part 2 Information" shall mean the patient records protected under 42 CFR Part 2, including, without limitation, substance use disorder (SUD) treatment records and other information covered by 42 CFR 2.1. In addition, any information protected under 42 CFR Part 2 that identifies an individual as having or having had a substance use disorder and that is created, received, or maintained by a Part 2 Program.
- e) Qualified Service Organization / QSO. "QSO" shall mean an entity that provides services to a Part 2 program, with obligations under 42 CFR 2.11, which for purposes of this Agreement may include Business Associate when Part 2 Information is involved.

## Obligations and Activities of Business Associate

Business Associate agrees to:

- a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law.
- b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement.
- c) Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware. The business associate's report will:
  - a. Identify the nature of the non-permitted or violating use or disclosure.
  - b. Identify the PHI used or disclosed.
  - c. Identify, if possible, who made the non-permitting or violating use or received the non-permitted or violating disclosure.
  - d. Identify any corrective action the business associate has taken or will take to prevent further disclosure.

- e. Identify any actions the business associate has taken or will take to mitigate any deleterious effect of the non-permitted or violating use or disclosure.
  - f. Provide any other information that the covered entity may reasonably request.
- d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information.
  - e) Make available to the covered entity, protected health information in a designated record as necessary to satisfy covered entity's obligations under 45 CFR 164.524. Access will be given within 2 weeks of covered entity's request.
  - f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity's obligations under 45 CFR 164.526. All amendments must be made within 2 weeks of notification.
  - g) Maintain and make available, within 2 weeks, the information required to provide an accounting of disclosures to the covered entity as necessary to satisfy covered entity's obligations under 45 CFR 164.528.
  - h) To the extent the business associate is to carry out one or more of covered entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and
  - i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPM Rules.

#### **Permitted Uses and Disclosures by Business Associate**

- a) Business associate may only use or disclose protected health information to perform functions, activities, or services for or on the behalf of the covered entity as specified in this document, provided that such use or disclosure would not violate the Privacy Rule or the minimum necessary policies and procedures.
- b) Business associate may use or disclose protected health information as required by law.
- c) Business associate agrees to make uses and disclosures and requests for protected health information consistent with covered entity's minimum necessary policies and procedures.
- d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity except for the specific uses and disclosures set forth below.
- e) Business associate may use protected health information for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.
- f) Business associate may disclose protected health information for the proper management and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law, or business associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies business associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- g) Business associate may provide data aggregation services relating to the health care operations of the covered entity.

### **Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**

- (a) Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity under 45 CFR 164.520, to the extent that such limitation may affect business associate's use or disclosure of protected health information.
- (b) Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate's use or disclosure of protected health information.
- (c) Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect business associate's use or disclosure of protected health information.

### **Permissible Requests by Covered Entity**

Covered entity shall not request business associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by covered entity.

### **Term and Termination**

(a) Term. The Term of this Agreement shall be effective as of the date signed below, and shall terminate only when all PHI provided to the business associate is destroyed or returned or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business associate authorizes termination of this Agreement by covered entity, if covered entity determines business associate has violated a material term of the Agreement and business associate has not cured the breach or ended the violation within the time specified by covered entity.

(c) Obligations of Business Associate upon Termination. Upon termination of this Agreement for any reason, business associate shall return to covered entity or, if agreed to by covered entity, destroy all protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, that the business associate still maintains in any form. Business associate shall retain no copies of the protected health information.

In the event that returning or destroying PHI is infeasible, written notification is to be provided of the conditions that make it impossible to return/destroy. Upon the written agreement that return or destruction of PHI is infeasible, the business associate will extend the protections of this agreement to such PHI and limit further use and disclosures of such PHI, for so long as the business associate maintains such PHI.

(d) Survival. The obligations of business associate under this Section shall survive the termination of this Agreement.

### **Miscellaneous**

a) Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

b) Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

c) Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

**Part 2 / Qualified Service Organization Agreement Addendum**

- a) Business Associate acknowledges that certain data it may receive is subject to Part 2 confidentiality requirements at 42 CFR Part 2.
- b) Business Associate shall not use or disclose Part 2 Information except as permitted by Part 2 and this Agreement.
- c) Business Associate understands and agrees that Part 2 Information may be disclosed only pursuant to a valid written patient consent or a court order that meets the requirements of 42 CFR 2.61.
- d) Business Associate understands and agrees that use or disclosure for purposes of civil, criminal, administrative, or legislative proceedings against a patient is prohibited absent consent or court order as required under 42 CFR 2.12.
- e) When Business Associate discloses Part 2 Information pursuant to this Agreement or consent, it shall include the appropriate Part 2 redisclosure statement as required by 42 CFR 2.32:  
  
"This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the individual to whom it pertains or as otherwise permitted by 42 CFR Part 2."
- f) Business Associate shall use appropriate safeguards and comply with Part 2 to prevent unauthorized uses and disclosures of any Part 2 Information other than as provided for by the Agreement.
- g) Business Associate shall report to Covered Entity any use or disclosure of Part 2 Information not permitted by this Agreement as required by Part 2 breach requirements.
- h) Business Associate shall ensure that any subcontractor or agent to whom it provides Part 2 Information agrees to contractually enter into obligations no less restrictive than those in this Agreement, in compliance with Part 2 requirements.
- i) Business Associate may use or disclose Part 2 Information as reasonably necessary to perform services for Covered Entity provided such use or disclosure would not violate Part 2 if done by the Covered Entity.
- j) Business Associate shall make reasonable efforts to limit PHI and Part 2 Information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

**Business Associate:**

*Rajeev Kumar*

Rajeev Kumar Nohria  
CEO, BetterDiagnostics, Inc.

**Covered Entity:**

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_