

Business Associate Agreement

INSTRUCTIONS:

- Read the Business Associate Agreement and sign.
 - Provide the name of one prescriber associated with the Covered Entity Address with National Provider Identifier and State License Number for validation purposes.
 - Add all sites covered by the BAA.
 - Upload all pages of the completed BAA to [JanssenCarePathPortal.com](https://www.janssen-carepath.com) or fax to 844-286-5444.
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This Business Associate Agreement (“BAA”) is entered into in connection with the Platform and Program Offerings (as defined below) made available by Johnson & Johnson (“J&J”) and is agreed between you (“Client” or “Covered Entity”) and Johnson & Johnson Health Care Systems Inc. (“JJHCS”) on behalf of itself and certain affiliates (collectively, “Company” or “Business Associate”). The Platform and Program Offerings provided by J&J are operated by JJHCS. Covered Entity and Company may be referred to individually as a “Party” or collectively as the “Parties.”

RECITALS

In connection with Janssen CarePath and/or J&J withMe (“Platform”) and the related patient support program offerings (“Program Offerings”), the Parties anticipate that it may be necessary for Company to receive, maintain, transmit, use, or disclose certain Protected Health Information (“PHI”) from, or on behalf of, Covered Entity that is subject to protection under the privacy, security, and breach notification requirements of the Health Insurance Portability and Accountability Act of 1996, as amended, including by the Health Information Technology for Economic & Clinical Health Act of the American Recovery and Reinvestment Act of 2009 (“HITECH Act”), certain regulations promulgated under HIPAA by the United States Department of Health and Human Services at 45 C.F.R. Parts 160 and 164, and certain regulations promulgated pursuant to the HITECH Act (collectively, “HIPAA”).

The purpose of this BAA is to help facilitate the Parties’ compliance with the requirements of HIPAA, as applicable when Company is acting as Covered Entity’s Business Associate, as the term is defined under HIPAA. Covered Entity acknowledges that Company may act in a capacity other than as a business associate and that this BAA only applies to the extent that Company is acting as a Business Associate for Covered Entity. Hereinafter, however, Company will be referred to as “Business Associate.”

NOW, THEREFORE, in consideration of the mutual promises and other consideration contained in this BAA, the delivery and sufficiency of which is hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. **Definitions.** Unless otherwise provided in this BAA, capitalized terms have the same meaning as set forth in HIPAA. “Applicable Law” means, in respect of any person, all provisions of constitutions, statutes, rules, regulations, and orders of governmental bodies or regulatory agencies applicable to such person, including, without limitation, HIPAA, and state privacy laws and security breach notification laws, and all orders and decrees of all courts and arbitrators in proceedings or actions to which the person in question is a party or by which it or its properties are bound.
2. **Applicability.** This BAA shall be applicable solely with respect to PHI that is received, maintained, transmitted, used, or disclosed by Business Associate in connection with the Platform and Program Offerings. This BAA shall not apply to patient data that has been released pursuant to a valid HIPAA authorization.
3. **Minimum Necessary Disclosures.** In accordance with HIPAA, Covered Entity shall limit its uses, disclosures, and requests of PHI to Business Associate to the minimum necessary to accomplish the Program Offerings Business Associate is performing for Covered Entity. Business Associate shall further limit its use, disclosures, and requests of PHI to the minimum necessary PHI to perform or have performed the services Business Associate is performing for Covered Entity. In each case, Covered Entity shall exercise reasonable judgment to determine what constitutes minimum necessary PHI.
4. **Scope of Use of PHI.** Business Associate shall not create, receive, maintain, transmit, use, or disclose PHI for any purpose other than as permitted or required by this BAA or as Required by Law.

5. **Permitted Uses and Disclosures.** Unless otherwise limited in this BAA, in addition to any other uses and/or disclosures permitted or required by this BAA, Business Associate may:

5.1 receive, maintain, transmit, use, and disclose PHI as necessary to provide the Platform and Program Offerings, including, but not limited to, providing benefits investigations, alternate coverage research, and research for prior authorization processes or administrative denial processes, location assistance for infusion sites (as appropriate), care coordination between sites of service (as appropriate), and other health care providers (such as specialty pharmacies), without limiting the foregoing, the care coordination services provided by the Business Associate with respect to Covered Entity's patients may include disclosing PHI to the specialty pharmacies used by such patients, or the business associate of the relevant specialty pharmacy, to confirm with the relevant specialty pharmacy that the patient has filled his or her prescription.

5.2 not use or disclose PHI in a manner that would violate Subpart E of 45 C.F.R. Part 164 if done by Covered Entity, except for the specific uses and disclosures set forth below.

5.3 create, receive, maintain, transmit, use, and disclose PHI for the proper management and administration of Business Associate, including, but not limited to, data analysis necessary to review, improve, or validate a product, feature, or service offered in connection with the services, or to carry out the legal responsibilities of Business Associate, provided that, (i) the disclosures are Required by Law, or (ii) any third party to which Business Associate discloses PHI provides written reasonable assurances in advance that: (a) the information will be held confidentially and used or further disclosed only for the purpose for which it was disclosed to the third party; and (b) the third party promptly will notify Business Associate of any instances of which it becomes aware in which the confidentiality of the PHI has been compromised.

5.4 create de-identified data sets from the PHI, provided that the method of de-identification complies with HIPAA (the "De-Identified Data"), and may disclose such De-Identified Data, solely for the benefit of Company for its independent uses and purposes, as permitted by applicable law.

5.5 provide data aggregation services relating to the health care operations of the Covered Entity.

6. **Safeguards for the Protection of PHI.** Business Associate shall (i) use reasonable safeguards that are designed to appropriately prevent the use or disclosure (other than as provided for by this BAA) of PHI, and (ii) implement administrative, physical and technical safeguards that are designed to reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic PHI. In all cases, Business Associate shall comply with the Security Rule requirements for business associates in 45 C.F.R. Parts 160 and 164 (Subparts A & C).

7. **Reporting of Unauthorized Uses or Disclosures.** In compliance with HIPAA, Business Associate shall report to Covered Entity:

7.1 any use or disclosure of PHI of which Business Associate becomes aware that is not provided for or permitted under this BAA.

7.2 any Security Incident of which Business Associate becomes aware; provided, however, that the Parties acknowledge and agree that this Section 7.2 constitutes notice by Business Associate to Covered Entity of the ongoing existence and occurrence of Unsuccessful Security Incidents for which no additional notice to Covered Entity shall be required. "Unsuccessful Security Incidents" means, without limitation, pings and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denial of service attacks, and any combination of the above, so long as no such incident results in unauthorized access, use, disclosure, modification or destruction of PHI or intentional interference with system operations in an information system that contains PHI.

7.3 any Breach of Unsecured PHI of which Business Associate becomes aware, without unreasonable delay and in no case later than ten (10) days following the discovery by Business Associate of such Breach. Business Associate shall provide Covered Entity with written notification of Breach in accordance with 45 C.F.R. § 164.410.

8. **Use of Subcontractors.** Business Associate shall cause each Subcontractor of Business Associate (including, without limitation, a Subcontractor that is an agent under Applicable Law) that creates, receives, maintains, transmits, uses, or discloses PHI on behalf of Covered Entity to sign a written agreement with Business Associate containing at least as restrictive provisions and conditions related to the protection of PHI as those that apply to Business Associate under this BAA. Business Associate shall only provide to a Subcontractor the minimum necessary PHI for the Subcontractor to perform or have performed the services the Subcontractor is performing for Business Associate.

9. **Authorized Access to and Amendment of PHI.** Only to the extent that Business Associate maintains PHI in Designated Record Sets, Business Associate shall (i) within fifteen (15) business days of a written request by Covered Entity for access to PHI about an Individual contained in any Designated Record Set of Covered Entity maintained by Business Associate, make available to Covered Entity in accordance with 45 C.F.R. § 164.524, all such PHI held by Business Associate, including

electronic access to PHI maintained by Business Associate in electronic form, and (ii) within thirty (30) business days of a written request by Covered Entity to amend PHI, incorporate any amendments Covered Entity makes to PHI in accordance with 45 C.F.R. § 164.526. In the event that Business Associate receives a request for access to PHI directly from an Individual, Business Associate shall direct the Individual to contact Covered Entity directly.

10. **Accounting of Disclosures of PHI.** Business Associate shall keep records of disclosures of PHI made by Business Associate (the "Disclosure Accounting") during the term of this BAA in accordance with 45 C.F.R. § 164.528. Business Associate shall provide the Disclosure Accounting to Covered Entity within fifteen (15) days of receiving a written request therefor from Covered Entity. Business Associate shall comply with, and assist Covered Entity in compliance with, additional requirements of 42 U.S.C. § 13405(c), if and when applicable. In the event that Business Associate receives a request for a Disclosure Accounting of PHI directly from an Individual, Business Associate shall direct the Individual to contact Covered Entity directly.

11. **Secretary, U.S. Dept. of Health and Human Services.** Business Associate shall make its internal practices, books and records related to the use and disclosure of PHI under this BAA available to the Secretary of the U.S. Department of Health and Human Services for the purpose of determining Covered Entity's compliance with 45 C.F.R. § 164.500 et seq.

12. **Privacy Obligations.** To the extent Business Associate is to carry out one or more of Covered Entity's obligations under Subpart E of 45 C.F.R. Part 164, Business Associate shall comply with the requirements of Subpart E that apply to Covered Entity in the performance of such obligation(s).

13. **Covered Entity Responsibilities.** Covered Entity warrants that it has obtained and will obtain any consents, Authorizations, and/or other legal permissions required under HIPAA and other Applicable Law for the disclosure of PHI to Business Associate. 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 PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI under this BAA. Covered Entity shall not agree to any restriction on the creation, receipt, maintenance, transmission, use, or disclosure of PHI under 45 C.F.R. § 164.522 that restricts Business Associate's creation, receipt, maintenance, transmission, use, or disclosure of PHI under this BAA unless such restriction is Required By Law or Business Associate grants its written consent to such restriction, which consent shall not be unreasonably withheld.

14. **Future Protections of PHI.** Upon the expiration or earlier termination of this BAA for any reason, if feasible, Business Associate shall return to Covered Entity, or, at Covered Entity's direction, destroy, all PHI in any form. If Business Associate determines that such return or destruction is not feasible, Business Associate shall extend the protections of this BAA to the PHI and shall limit further creation, receipt, maintenance, transmission, use, or disclosure to those purposes that make the return or destruction of the PHI infeasible.

15. **Termination.** Either Party (the "Non-Breaching Party") may terminate this BAA upon 30 days' prior written notice to the other party (the "Breaching Party") in the event that the Breaching Party materially breaches this BAA and such breach is not cured to the reasonable satisfaction of the Non-Breaching Party within such 30-day period. In the event of termination of this BAA, either Party may terminate those portions of the BAA, and only those portions of the BAA, that require Business Associate to create, receive, maintain, transmit, use, or disclose PHI, in accordance with and subject to any rights to cure and payment obligations specified in the BAA. Additionally, this BAA will terminate or transfer, as applicable, upon notification to Covered Entity of the establishment of a successor Business Associate, and the transfer from Business Associate to successor Business Associate.

16. **Liability.** This BAA is exclusively governed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L.104-191,110 Stat.1936, enacted August 21, 1996), including all rights, remedies and requirements set forth therein. Consistent with HIPAA, Covered Entity hereby acknowledges and agrees that HIPAA does not confer a private cause of action on entities or individuals affected by healthcare privacy breaches and, as such, hereby waives the right to bring any claims, including civil claim(s) against Company or its subcontractors for damages (including without limitation, direct, indirect, special, or consequential) in relation to a healthcare privacy or any other breach of this BAA.

17. **No Intended Third Party Beneficiaries.** Nothing express or implied in this BAA is intended to confer, nor shall anything herein confer, upon any person other than Covered Entity and Company, and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

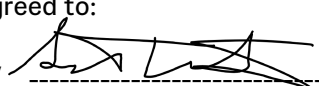
18. **Independent Contractor Status.** The Parties acknowledge and agree that Business Associate is at all times acting as an independent contractor of Covered Entity and not as an agent or employee of Covered Entity under this BAA.

19. **Assignment.** Company may assign this BAA with notice to Covered Entity. Covered Entity may assign this BAA with the prior written consent of Company. The assignment of this BAA, in whole or in part, to any majority- owned subsidiary in the United States or to a successor organization by merger or acquisition does not require the consent of the other. It is not considered an assignment for Business Associate to divest a portion of its business in a manner that similarly affects all Covered Entities.

20. **Future Amendments.** Any future amendments to HIPAA affecting the required provisions of business associate agreements are hereby incorporated by reference into this BAA as if set forth in this BAA in their entirety, effective on the later of the effective date of this BAA or such subsequent date as may be specified by HIPAA. No other amendment to this BAA shall be valid unless agreed to in writing by both Parties.

21. **Entire Agreement.** This BAA, together with the Terms of Use, constitute the entire agreement between the Parties with regard to the subject matter hereof, and supersede all prior agreements and understandings, oral or written, with regard to such subject matter, including replacing any business associate agreement that Covered Entity may have entered into in the past with International Business Machines Corp. related to the Platform and Program Offerings.

Each Party accepts the terms of this BAA by signing this BAA electronically, by a duly authorized representative of the Party. By signing below, Covered Entity represents and warrants that, other than the requested information in the signature block and listed prescribers and sites, this BAA is being signed as-is and that the terms and conditions of this BAA have not been modified in any way. Any attempt to do so is void. If there is a conflict between the terms of this BAA and the BAA available on the website, the terms and conditions of the BAA on the website shall prevail.

<p>Agreed to:</p> <p>By _____ Authorized signature</p> <p>Covered Entity Company Name*: _____</p> <p>Title*:</p> <p>Name (type or print)*:</p> <p>Date*:</p> <p>Time of Signature*:</p> <p>Covered Entity Address*:</p> <p>Covered Entity Email Address*:</p> <p>Covered Entity Phone Number*:</p> <p>Covered Entity Fax Number*:</p> <p>Please provide the name of one prescriber associated with the Covered Entity Address above with National Provider Identifier and State License Number for validation purposes.</p> <p>Prescriber Name*:</p> <p>NPI*:</p> <p>SLN*:</p> <p>*Required Fields</p>	<p>Agreed to:</p> <p>By  Authorized signature</p> <p>Company:</p> <p>Johnson & Johnson Health Care Systems Inc. on behalf of itself and certain affiliates</p> <p>Title: COO, NA Innovative Medicine</p> <p>Name (type or print): Scott White</p> <p>Date: 12/16/2024</p> <p>Time of Signature: 1:10 PM ET</p>
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Please add all sites covered by the BAA by populating the required fields below.

Site Name:
Address:
City:
State:
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Fax Number:

Site Name:
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Upload all pages of the signed BAA to www.JanssenCarePathPortal.com or fax to 844-286-5444