Business Associate Agreement



- Read the Business Associate Agreement and sign.
- Provide the name of one prescriber associated with the Client Address with National Provider Identifier and State License Number for validation purposes.
- Add all sites covered by the Business Associate Agreement and complete all required fields.
- Upload all pages of the completed and signed Business Associate Agreement to JanssenCarePathPortal.com or fax to 844-286-5444

This Business Associate Agreement ("Agreement") is in connection with your use of Janssen CarePath and is agreed between you ("Client") and International Business Machines Corporation ("IBM"). Janssen CarePath is operated by Johnson & Johnson Health Care Systems Inc. ("Janssen"). Janssen has contracted the management of Janssen CarePath, including any Protected Health Information (as defined below), that may be hosted on the Platform, to IBM. IBM and Client may be referred to individually as a "Party" or collectively as the "Parties."

This Agreement applies to IBM and Client and their respective Enterprise companies who avail themselves of this Agreement. The parties shall coordinate the activities of Enterprise companies under this Agreement. Enterprise companies are defined as entities that Client or IBM control, or under common control, by owning greater than 50% of the voting shares. This Agreement supplements and is made part of the Terms of Use you agreed to in relation to accessing and creating a Janssen CarePath account.

RECITALS

Client is a "Covered Entity," as such term is defined by HIPAA (defined below).

In connection with the Services being provided pursuant to Janssen CarePath, the Parties anticipate that it may be necessary for IBM to create, receive, maintain, transmit, use, or disclose certain Protected Health Information from, or on behalf of, Client ("Client PHI") 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 Agreement is to help facilitate the Parties' compliance with the requirements of HIPAA, as applicable when IBM is acting as Client's Business Associate, as the term is defined under HIPAA.

Client acknowledges that IBM may act in a capacity other than as a business associate and that this Agreement only applies to the extent that IBM is acting as a Business Associate for Client. Hereinafter, however, IBM will be referred to as "Business Associate."

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

AGREEMENT

- **Definitions.** Unless otherwise provided in this Agreement, 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 Agreement shall be applicable solely with respect to Client PHI that is created, received, maintained, transmitted, used, or disclosed by Business Associate in connection with the Services provided pursuant to Janssen CarePath. In the event that IBM is no longer managing Janssen CarePath on behalf of Janssen, Janssen will notify Client of the change and provide the name of the entity who will be the new Business Associate ("Successor Business Associate"). In such event, Client directs IBM to timely provide the Successor Business Associate all of the PHI of Client that is created, received, maintained, transmitted, used, or disclosed by Business Associate in connection with the services provided pursuant to Janssen CarePath such that Services to Client will not be interrupted or negatively affected. Client agrees to timely enter into a new Business Associate Agreement with the Successor Business Associate.
- 3. Minimum Necessary Standards. In accordance with HIPAA, Client shall limit its uses, disclosures, and requests of Client PHI to Business Associate to the minimum necessary to accomplish the Services Business Associate is performing for Client. Business Associate shall further limit its use, disclosures, and requests of Client PHI to the minimum necessary Client PHI to perform or have performed the services Business Associate is performing for Client. In each case, Client shall exercise reasonable judgment to determine what constitutes minimum necessary Client PHI.
- **Scope of Use of Client PHI.** Business Associate shall not create, receive, maintain, transmit, use, or disclose Client PHI for any purpose other than as permitted or required by this Agreement or as Required by Law.
- **Permitted Uses and Disclosures.** Unless otherwise limited in this Agreement, in addition to any other uses and/or disclosures permitted or required by this Agreement, Business Associate may:
 - 5.1 create, receive, maintain, transmit, use, and disclose Client PHI as necessary to provide the services and perform its obligations as required to perform the services for Janssen CarePath, including, but not limited to, providing benefits investigations, alternate coverage research, and research for prior authorization

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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 Company 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 create, receive, maintain, transmit, use, and disclose Client 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, with respect to disclosures, (i) the disclosures are Required by Law, or (ii) any third party to which Business Associate discloses Client 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 Client PHI has been compromised.
- 5.3 create de-identified data sets from the Client PHI, provided that the method of deidentification complies with HIPAA (the "De-Identified Data"), and may disclose such De-Identified Data, solely for the benefit of Janssen for their independent uses and purposes, as permitted by applicable law.
- **Safeguards for the Protection of Client 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 Agreement) of Client PHI, and (ii) implement administrative, physical and technical safeguards that are designed to reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Client 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).
- **Reporting of Unauthorized Uses or Disclosures.** In compliance with HIPAA, Business Associate shall report to Client:
 - 7.1 any use or disclosure of Client PHI of which Business Associate becomes aware that is not provided for or permitted under this Agreement.
 - 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 Client of the ongoing existence and occurrence of Unsuccessful Security Incidents for which no additional notice to Client 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 Client PHI or intentional interference with system operations in an information system that contains Client PHI.
 - any Breach of Unsecured Client 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 Client with written notification of Breach in accordance with 45 C.F.R. § 164.410.

- 8. <u>Use of Subcontractors</u>. 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 Client PHI on behalf of Client to sign a written agreement with Business Associate containing at least as restrictive provisions and conditions related to the protection of Client PHI as those that apply to Business Associate under this Agreement. 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 Client PHI. Only to the extent that Business Associate maintains Client PHI in Designated Record Sets, Business Associate shall (i) within fifteen (15) business days of a written request by Client for access to Client PHI about an Individual contained in any Designated Record Set of Client maintained by Business Associate, make available to Client in accordance with 45 C.F.R. § 164.524, all such Client PHI held by Business Associate, including electronic access to Client PHI maintained by Business Associate in electronic form, and (ii) within thirty (30) business days of a written request by Client to amend Client PHI, incorporate any amendments Client makes to Client PHI in accordance with 45 C.F.R. § 164.526. In the event that Business Associate receives a request for access to Client PHI directly from an Individual, Business Associate shall direct the Individual to contact Client directly.
- **Accounting of Disclosures of Client PHI.** Business Associate shall keep records of disclosures of Client PHI made by Business Associate (the "Disclosure Accounting") during the term of this Agreement in accordance with 45 C.F.R. § 164.528. Business Associate shall provide the Disclosure Accounting to Client within fifteen (15) days of receiving a written request therefor from Client. Business Associate shall comply with, and assist Client 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 Client PHI directly from an Individual, Business Associate shall direct the Individual to contact Client directly.
- 11. <u>Secretary, U.S. Dept. of Health and Human Services</u>. Business Associate shall make its internal practices, books and records related to the use and disclosure of Client PHI under this Agreement available to the Secretary of the U.S. Department of Health and Human Services for the purpose of determining Client's compliance with 45 C.F.R. § 164.500 et seq.
- **Client Responsibilities.** Client warrants that it has obtained or will obtain any consents, Authorizations, and/or other legal permissions required under HIPAA and other Applicable Law for the disclosure of Client PHI to Business Associate. Client 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 Client PHI under this Agreement. Client 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 Client PHI under this Agreement unless such restriction is Required By Law or Business Associate grants its written consent to such restriction, which consent shall not be unreasonably withheld.
- **13. Future Protections of Client PHI.** Upon the expiration or earlier termination of this Agreement for any reason, if feasible, Business Associate shall return to Client, or, at Client's

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direction, destroy, all Client PHI in any form. If Business Associate determines that such return or destruction is not feasible, Business Associate shall extend the protections of this Agreement to the Client PHI and shall limit further creation, receipt, maintenance, transmission, use, or disclosure to those purposes that make the return or destruction of the Client PHI infeasible.

- 14. Termination. Either Party (the "Non-Breaching Party") may terminate this Agreement upon 30 days' prior written notice to the other party (the "Breaching Party") in the event that the Breaching Party materially breaches this Agreement 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 Agreement, either Party may terminate those portions of the Agreement, and only those portions of the Agreement, that require Business Associate to create, receive, maintain, transmit, use, or disclose Client PHI, in accordance with and subject to any rights to cure and payment obligations specified in the Agreement. Additionally, this Agreement will terminate upon notification to Client of the establishment of a Successor Business Associate, and the transfer from Business Associate to Successor Business Associate.
- **15. 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, and the laws of the State of New York to govern, interpret, and enforce all of the parties' respective rights, duties, and obligations arising from, or relating to, the subject of this Agreement, without regard to conflict of law principles.

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 IBM 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 Agreement.

- **No Intended Third Party Beneficiaries.** Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Client and IBM, and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.
- **17.** Independent Contractor Status. The Parties acknowledge and agree that Business Associate is at all times acting as an independent contractor of Client and not as an agent or employee of Client under this Agreement.
- **Assignment.** Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other. Any attempt to do so is void. Neither Party will unreasonably withhold such consent. The assignment of this Agreement, 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 of its Clients.
- **19. Future Amendments.** Any future amendments to HIPAA affecting the required provisions of business associate agreements are hereby incorporated by reference into this Agreement as if set forth in this Agreement in their entirety, effective on the later of the effective date of this Agreement or such subsequent date as may be specified by HIPAA. No other amendment to this Agreement shall be valid unless agreed to in writing by both Parties.

Each Party accepts the terms of this Business Associate Agreement by signing this Agreement electronically, by a duly authorized representative of the Party.

By signing below, Client represents and warrants that, other than the requested information in the signature block and listed prescribers and sites, this Agreement is being signed as-is and that the terms and conditions of this Agreement have not been modified in any way. Any attempt to do so is void. If there is a conflict between the terms of this Agreement and the Agreement available on the website, the terms and conditions of the Agreement on the website shall prevail.

Agreed to:	Agreed to:		
By*:	By:Authorized signature		
Signature Authorized by Site Compliance Officer	Authorized Signature		
Client Company Name*:	IBM:		
	International Business Machines Corporation		
Title*:	Title: Client Partner, IBM Consulting		
Name (type or print) *:	Name (type or print): Shankar lyer		
Date*:	Date and Time of Signature:		
Time of Signature*:			
Client Postal Address*:			
Client Business (i.e. Not Personal) Email*			
Address*:			
Client Phone Number*:			
Client Fax Number*:			
Please provide the name of one prescriber associated wi Provider Identifier and State License Number for validation			
Prescriber Name*: NPI*: SLN*: *Required Fields			

Please proceed to the next page.

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Site Name: Address: City: State: Zip: Phone Number: Fax Number:			
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Please add all sites covered by the Business Associate Agreement by populating the required fields

Please proceed to the next page.

Site Name: Address: City: State: Zip: Phone Number: Fax Number:		
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Upload all pages of the completed and signed Business Associate Agreement to www.JanssenCarePathPortal.com or fax to 844-286-5444