THE CHILDREN'S MERCY HOSPITAL
BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (this “Agreement”) is entered into by and between The Children’s Mercy Hospital, a Missouri nonprofit corporation, with its principal place of business at 2401 Gillham Road, Kansas City, Missouri 64108 ("Buyer" or “Covered Entity”), and the Vendor identified in Buyer’s applicable Purchase Order (“Vendor” or “Business Associate”).

RECITALS

WHEREAS, Covered Entity and Vendor are parties to an arrangement(s) or separate agreement(s) (collectively, the “Business Relationship”) under which Vendor provides certain goods and/or services to Covered Entity; and

WHEREAS, In order for the parties to perform under the Business Relationship, Covered Entity may disclose to Vendor PHI, and such disclosure may result in Vendor’s use, disclosure, maintenance and/or creation of PHI, including Electronic Protected Health Information (“ePHI”), on behalf of Covered Entity; and

WHEREAS, Vendor’s provision of services to Covered Entity, when coupled with Vendor’s creation, receipt, maintenance or transmission of PHI from, for or on behalf of Covered Entity, may qualify Vendor a “Business Associate” of Covered Entity under the HIPAA Rules; and

WHEREAS, Covered Entity’s disclosure of PHI to a “Business Associate”, and a “Business Associate’s” use, disclosure and creation of PHI for or on behalf of Covered Entity, is subject to protection and regulation under the HIPAA Rules; and

WHEREAS, To the extent Vendor qualifies as a “Business Associate” of Covered Entity in connection with the Business Relationship, the parties have executed this Agreement to set forth and confirm their agreement to comply with their respective obligations under HIPAA and HITECH.

NOW, THEREFORE, in consideration of the covenants and agreements set forth herein, Covered Entity and Business Associate agree as follows:

1. Definitions.

(a) Unless otherwise provided in this Agreement, capitalized terms have the same meanings as set forth in the HIPAA Rules, including but not limited to: Breach, Data Aggregation, Designated Record Set, Disclosure, Electronic Protected Health Information, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, and Unsecured Protected Health Information.

(b) “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 the Business Associate identified in the opening paragraph of this Agreement.

(c) “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 Covered Entity identified in the opening paragraph of this Agreement.

(d) “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Parts 160 and 164.

(e) “HITECH” shall mean the Health Information Technology for Economic and Clinical Health Act, set forth in Division A, Title XIII, of the American Recovery and Reinvestment Act of 2009, and its implementing regulations and guidance that: (i) affect the relationship between a Business Associate and Covered Entity; and (ii) provide direction to Covered Entity in regard to its obligation to comply with HITECH’s requirements to notify affected individuals in the event of a Breach of Unsecured Protected Health Information.

(f) “PHI” means “Protected Health Information,” as that term is defined in the HIPAA Rules. PHI includes PHI that is ePHI as well as PHI that does not constitute ePHI.

2. Permitted Uses and Disclosures by Business Associate.

(a) In General. Except as otherwise limited in this Agreement or by law, Business Associate may use or disclose PHI created, received, maintained, or transmitted from, for or on behalf of Covered Entity only as necessary to perform the functions, activities, or services that are specified in the Business Relationship. Business Associate may not use or further disclose PHI in a manner that would violate the HIPAA Rules if such use or disclosure were done by Covered Entity, except for the specific uses and disclosures set forth below:
(i) Management and Administration: Legal Responsibilities.

a. Business Associate may use PHI if necessary for the proper management and administration of Business Associate, or to carry out the legal responsibilities of Business Associate.

b. Business Associate may disclose PHI if necessary for the proper management and administration of Business Associate, or to carry out the legal responsibilities of Business Associate, if:

i. the disclosure is Required By Law, or

ii. Business Associate obtains reasonable assurances, in writing, from the person to whom the information is disclosed that it will remain confidential and be used or further disclosed only as Required By Law or for the purposes for which it was disclosed to the person, and that such person will notify Business Associate, in writing, within five (5) business days, of any instances of which it is aware in which the confidentiality of the information has been breached.

(ii) Data Aggregation. Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 45 CFR § 164.504(e)(2)(i)(B).

(b) Required by Law. Business Associate may use or disclose PHI as Required By Law.

(c) Limitation on Use and Disclosure of PHI. With regard to its use, disclosure or request of PHI necessary to perform its obligations to Covered Entity, Business Associate agrees to limit such use, disclosure or request of PHI to the Minimum Necessary to accomplish the intended purpose of the use, disclosure or request, respectively, whenever the HIPAA Rules limits the use or disclosure in question to the Minimum Necessary.

(d) De-identified PHI. Business Associate may de-identify PHI in accordance with 45 CFR 164.514 solely as necessary for Business Associate to fulfill its obligations under the Business Relationship. Business Associate shall not use de-identified PHI for any purpose other than as required to fulfill its duties under the Business Relationship.

3. Obligations of Business Associate.

(a) In General. Business Associate shall not use or further disclose PHI other than as permitted or required by this Agreement or as Required By Law. Business Associate shall not transmit PHI to, or process or maintain PHI in, any country outside of the United States without the prior written consent of the Covered Entity.

(b) Safeguards. Business Associate shall use reasonable and appropriate safeguards and comply, where applicable, with Subpart C of 45 CFR Part 164 with respect to ePHI, to prevent use or disclosure of PHI other than as specifically authorized by this Agreement. Such safeguards shall at a minimum include: (i) a comprehensive written information privacy and security policy addressing the requirements of the HIPAA Rules that are directly applicable to Business Associate; and (ii) periodic and mandatory privacy and security training and awareness for members of Business Associate’s Workforce.

(c) Subcontractors. In accordance with 45 CFR § 164.502(c)(1)(ii) and 164.308(b)(2) (if applicable), Business Associate shall require Subcontractors that create, receive, maintain, or transmit PHI on behalf of Business Associate to agree, in writing, to the same restrictions and conditions that apply to Business Associate with respect to such information.

(d) Access to PHI. Business Associate shall provide to Covered Entity, at Covered Entity’s request and in the time and manner Covered Entity reasonably specifies but in no case longer than ten (10) business days, PHI in a Designated Record Set as necessary for Covered Entity to respond to Individuals’ requests for access to PHI about them under 45 CFR § 164.524. If any Individual to whom the PHI relates directly requests access to such PHI from the Business Associate, Business Associate shall notify Covered Entity and provide all relevant information to Covered Entity without unreasonable delay, but in any event within twenty (20) days of such request, necessary for Covered Entity to fulfill the request.

(e) Amendment to PHI. Business Associate shall, upon receipt of notice from Covered Entity but in no case longer than ten (10) business days, make available PHI in a Designated Record Set to Covered Entity for amendment and incorporate any amendments to the PHI in accordance with 45 CFR § 164.526, or take other measures as necessary to satisfy Covered Entity’s obligations under 45 CFR § 164.526. If any Individual to whom the PHI relates directly requests access to such PHI from the Business Associate, Business Associate shall notify Covered Entity and provide all relevant information to Covered Entity without unreasonable delay, but in any event within twenty (20) days of such request, necessary for Covered Entity to fulfill the request.

(f) Accounting of Disclosures of PHI. Business Associate shall document its disclosures of PHI and information related to those disclosures in a manner that would enable Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. § 164.528. Such information must be maintained by Business Associate
for a period of six (6) years. Business Associate shall provide to Covered Entity, in the time and manner Covered Entity reasonably specifies but in no case longer than ten (10) business days, the information required for Covered Entity to provide an accounting of disclosures in accordance with 45 CFR § 164.528. If any Individual to whom the PHI relates directly requests that the Business Associate provide an accounting of Disclosure(s) of such PHI Business Associate shall notify Covered Entity and provide all relevant information to Covered Entity without unreasonable delay, but in any event within twenty (20) days of such request, necessary for Covered Entity to fulfill the request.

(g) Standard Transactions. Business Associate shall comply with each applicable requirement of 45 C.F.R. Parts 160 and 162 if Business Associate conducts Standard Transactions for or on behalf of Covered Entity.

(h) Performance of Business Associate. To the extent Business Associate is to carry out any 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 of 45 C.F.R. Part 164 that apply to Covered Entity in the performance of such obligation.

(i) Auditing and Inspections. Business Associate shall make available to the Secretary of Health and Human Services Business Associate’s internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, for purposes of determining Covered Entity’s and Business Associate’s compliance with the HIPAA Rules. Unless otherwise Required by Law or by the Secretary, Business Associate shall immediately notify Covered Entity upon receipt by Business Associate of any such request, and shall provide Covered Entity with copies of all materials provided by Business Associate to HHS.

(j) Security of PHI. Business Associate agrees to comply with all applicable security requirements under the HIPAA Rules, including the requirements to maintain appropriate and reasonable administrative, physical, and technical safeguards, including documentation of the same, so as to ensure that PHI is not used or disclosed other than as provided by this Agreement or as Required By Law. Specifically, and without limitation, Business Associate shall take the following actions and implement the following safeguards:

(i) Administrative safeguards (implementation of policies and procedures to prevent, detect, contain, and correct security violations; conduct and documentation of risk analyses and risk management);

(ii) Physical safeguards (implementation of policies and procedures to limit physical access to PHI or electronic information systems and related facilities);

(iii) Technical safeguards (implementation of policies and procedures creating and tracking unique user identification, authentication processes, and transmission security, which may include encryption); and

(iv) Adoption and implementation of policies and procedures to reasonably and appropriately document the foregoing safeguards as required by the Security Rule.

(k) Security Questionnaire. Business Associate will complete and submit to Covered Entity the System Security Questionnaire provided by Covered Entity to Business Associate. Covered Entity does not anticipate disclosing PHI to Business Associate until Covered Entity has verified Business Associate’s security safeguards meet the HIPAA Rule’s security standards and such security safeguards are in place.

(l) Mitigation. Business Associate shall mitigate any harmful effect that is known to Business Associate of any use or disclosure of PHI by Business Associate that violates the requirements of this Agreement or applicable law.

(m) Reporting Breaches of Unsecured PHI and/or Security Incidents. Business Associate shall report to Covered Entity any actual or suspected use or disclosure of PHI that is not authorized by this Agreement of which Business Associate becomes aware, including Breaches of Unsecured PHI as required by 45 CFR § 164.410 and any Security Incident, without unreasonable delay but in any event within five (5) business days after Business Associate becomes aware thereof.

(i) Notification of Security Incidents and Breach of Unsecured PHI. Business Associate shall provide the reporting required under Section 3(m) of this Agreement via written notification to Covered Entity. The notice shall include: (i) the identification of each Individual whose PHI or Unsecured PHI has been or is reasonably believed by Business Associate to have been accessed, acquired, used or disclosed during the Breach or Security Incident, (ii) a brief description of the Breach or Security Incident, including the date of the Breach or Security Incident and the date of the Business Associate’s discovery of the Breach or Security Incident, (iii) a description of the types of PHI or Unsecured PHI that were involved in the Breach or Security Incident (such as whether name, date of birth, social security number, home address, account number, diagnosis, disability code, or other types of information are involved), (iv) what steps the affected Individuals should take to protect themselves from potential harm, (iv) any preliminary steps taken by Business Associate to mitigate any harm caused by the Breach or Security Incident, and (v) a description of any investigatory steps taken by Business Associate and the results thereof. In addition, Business Associate shall provide any additional information reasonably requested by Covered Entity for purposes of investigating or mitigating potential harm caused by a Breach of Unsecured PHI. A Breach shall be treated as discovered by Business Associate as of the first day on which the Breach is known to Business
Associate (including any person, other than the Individual committing the Breach, that is an employee, officer, or other agent of Business Associate) or should reasonably have been known to Business Associate to have occurred. Covered Entity shall have the sole right to determine, with respect to a Breach: (i) whether notice is to be provided to Individuals, regulators, law enforcement agencies, consumer reporting agencies, media outlets and/or the Department of Health and Human Services, or others as Required By Law or regulation, in Covered Entity’s discretion; (ii) the contents of any such notices, (iii) whether any type of remediation may be offered to Individuals affected, and (iv) the nature and extent of any such remediation. The delivery of notices to affected Individuals and government agencies, media and/or other entities as Covered Entity reasonably determines to be required, and any investigation and remediation which Covered Entity determines is required or reasonably necessary, shall be at Business Associate’s sole cost and expense.

(n) Responding to Requests for Access, Use or Exchange of Electronic Health Information. Business Associate understands and acknowledges that Covered Entity is an Actor subject to the requirements of the Information Blocking Regulations codified at 45 C.F.R. Part 171, enacted to implement the information blocking provisions of the 21st Century Cures Act (Public Law No: 114-255) (hereinafter, “IB Law”). For purposes of this Section 3(n), Access, Use, Exchange and Electronic Health Information shall have the meaning ascribed to them in the IB Law. In order to ensure the consistent and non-discriminatory approach to Access, Use and Exchange of Electronic Health Information in conformity with the IB Law, Covered Entity, to the extent permissible, wishes to be responsible for the application of the IB Law to specific requests and the parties agree as follows:

(i) To the extent that the specific functions, activities or services Business Associate performs for or on Covered Entity’s behalf pursuant to the Business Relationship require Business Associate to respond directly to requests for Access, Use or Exchange of Electronic Health Information, Business Associate shall comply with the requirements of the IB Law when responding to such requests.

(ii) If the specific functions, activities or services Business Associate performs for or on Covered Entity’s behalf pursuant to the Business Relationship do not require Business Associate to respond directly to requests for Access, Use or Exchange of Electronic Health Information or Business Associate receives (i) a request for access to Covered Entity’s PHI in Business Associate’s control or possession pursuant to 45 C.F.R. 164.524, (ii) a request pursuant to an authorization for the disclosure of Covered Entity’s PHI in Business Associate’s control or possession pursuant to 45 C.F.R. 164.508, or (iii) any other request for the disclosure of Covered Entity’s PHI in Business Associate’s control or possession from a person or entity other than Covered Entity that is outside the scope of any functions, activities or services the Business Associate performs for or on Covered Entity’s behalf pursuant to the Business Relationship, the Business Associate shall not be obligated to respond on Covered Entity’s behalf and shall promptly forward such request to Covered Entity. Covered Entity shall be wholly responsible for assessing and responding to such requests in accordance with applicable law, including, but not limited to the IB Law. The foregoing shall not restrict Business Associate’s ability to respond to requests made of Business Associate where Business Associate has a legal obligation to fulfill the request not arising as a result of the Business Relationship.

(iii) So long as, Business Associate is acting as Covered Entity’s business associate, this section shall apply and govern the relationship between the parties with respect to responding to requests for Access, Use or Exchange of Electronic Health Information that is Covered Entity’s PHI in Business Associate’s control or possession as a result of this Agreement regardless of whether or not the Business Associate is also an Actor subject to the IB Law in its own right.

4. Obligations of Covered Entity:

(a) Notice of Privacy Practices. Business Associate acknowledges the receipt of Covered Entity’s Notice of Privacy Practices, as may be amended from time to time, accessible at childrensmercy.org or by request to privacyofficer@cbmb.edu.

(b) Changes in Permission by Individual. Covered Entity will notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI to the extent that the change may affect Business Associate’s use or disclosure of PHI.

(c) Restriction on Use/Disclosure of PHI. Covered Entity will notify Business Associate of any restriction on the use or disclosure of PHI that has been agreed to with an Individual and any restrictions on marketing or fundraising to the extent that the restriction may affect Business Associate’s use or disclosure of PHI.

(d) Permissible Requests. Covered Entity will not request Business Associate to use or disclose PHI in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by Covered Entity, except as specifically permitted under Section 2 above.

5. Indemnification. Business Associate agrees to indemnify, defend and hold harmless Covered Entity and its directors, officers, Workforce members, employees and agents (each, a “Covered Entity Indemnitee”) from and against any and all Losses (as defined below) in connection with any breach of this Agreement or any negligent or wrongful acts or omissions by Business Associate or its employees, Subcontractors or agents. “Losses” shall mean any and all losses, liabilities, judgments, damages, fines, penalties, costs or expenses
Term and Termination.

(a) **Term of the Agreement.** The term of this Agreement begins on the Effective Date and ends when all of the PHI provided to Business Associate by or on behalf of Covered Entity, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity. To the extent it is infeasible for Business Associate to return or destroy the PHI, protections shall be extended to that PHI in accordance with the termination provisions in this Section.

(b) **Termination for Breach.** Covered Entity may immediately terminate this Agreement:

(i) If Covered Entity determines that Business Associate has violated a material term of this Agreement and Business Associate has not cured the breach or ended the violation within the time specified by Covered Entity, not to exceed thirty (30) days;

(ii) If Business Associate is named as a defendant in a criminal proceeding resulting from an alleged violation of the HIPAA Rules or if there is a finding or stipulation by any governmental authority or in any proceeding (civil or criminal) that Business Associate has violated any standard or requirement of the HIPAA Rules or other security or privacy law; or

(iii) Pursuant to Section 8, below.

(c) **Automatic Termination.** This Agreement will automatically terminate on the date Business Associate ceases to provide the services described in the Business Relationship.

(d) **Effect of Termination.** Upon termination of this Agreement, Business Associate will return or destroy all PHI received from Covered Entity or created or received by Business Associate on behalf of Covered Entity that Business Associate still maintains and will retain no copies of that PHI. However, if such return or destruction is not feasible, Business Associate will notify Covered Entity of such infeasibility in writing, and extend the protections of this Agreement to such PHI and will limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible. The obligations of Business Associate under this Section shall survive termination of this Agreement.

8. **Amendment to Comply with Law.** Covered Entity and Business Associate agree to negotiate in good faith any amendments to this Agreement from time to time as is necessary for Covered Entity and Business Associate to comply with the requirements of the HIPAA Rules, HITECH, and any other applicable implementing regulations or guidance. Covered Entity may terminate this Agreement upon prior written notice in the event: (1) Business Associate does not promptly enter into negotiations to amend this Agreement when requested by Covered Entity under this Section; or (2) Business Associate does not enter into an amendment of this Agreement providing assurances regarding the safeguarding of PHI that Covered Entity, in its sole discretion, deems sufficient to satisfy applicable law, regulation or guidance.

9. **Regulatory References.** A reference in this Agreement to a section in the HIPAA Rules and any other laws shall mean the referenced section as is currently drafted and as it may be subsequently amended.

10. **Interpretation.** Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the HIPAA Rules.

11. **Survival.** All provisions of this Agreement that by their nature must survive termination in order to have their objectively intended effect, shall survive the termination of this Agreement. No termination hereof shall excuse or release a party from any breach hereof occurring prior to such termination.

12. **No Third Party Beneficiaries.** This Agreement is for the sole benefit of the parties hereto and their respective permitted successors and permitted assigns. No provision of this Agreement, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit, or remedy of any nature whatsoever.

13. **Independent Contractors.** Each party is an independent contractor relative to the other party, and nothing herein shall be construed to create a partnership, joint venture, agency or other relationship between the parties other than the contractual relationship expressly set
forth herein. For the avoidance of doubt, it is not intended that an agency relationship (as determined under the Federal common law of agency) be established hereby expressly or by implication between Covered Entity and Business Associate under the HIPAA Rules.

14. **Assignment.** This Agreement may not be assigned or any duties hereunder delegated by either party without the prior written consent of the other party; provided, however, that Covered Entity may assign this Agreement and any of its rights or obligations hereunder to any subsidiary or affiliate of Covered Entity or to any successor in the case of a merger, combination or sale of some or all of the assets of Covered Entity. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective permitted successors and permitted assigns.

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