

**HEALTH INFORMATION EXCHANGE HOSPITAL PARTICIPATION AGREEMENT
BETWEEN THE
GOVERNOR'S OFFICE OF ELECTRONIC HEALTH INFORMATION
AND**

This Health Information Exchange Hospital Participation Agreement (the "Agreement") is entered into between the Commonwealth of Kentucky, Cabinet for Health and Family Services, Governor's Office of Electronic Health Information ("GOEHI"), and the _____ having its principal place of business at _____, Kentucky (each a "Party" and collectively the "Parties").

WHEREAS, GOEHI is a governmental agency within the Cabinet for Health and Family Services, which was created by Executive Order 2009-770 issued by Governor Steve Beshear to provide leadership for the development of the Kentucky Health Information Exchange ("Exchange").

WHEREAS, GOEHI has established the Exchange to facilitate health information sharing for Treatment, Payment, Operations, and to facilitate "meaningful use" of Protected Health Information through the Exchange in a manner that complies with all applicable laws and regulations, including without limitation those protective to the privacy and security of health information.

WHEREAS, GOEHI places an emphasis on electronic health technology as a means of improving patient care, reducing medical errors and making more efficient use of health care dollars by reducing redundant and duplicative services.

WHEREAS, GOEHI has and will enter into Health Information Exchange Participation Agreements ("HIE Participation Agreements") with other Health Care Providers, as defined herein, referred to in this Agreement as "Participants."

WHEREAS, Participants have a common interest in improving patient care, reducing medical errors and making more efficient use of health care dollars by reducing redundant and duplicative services.

WHEREAS, Participants intend to be meaningful users of electronic health record technology as such terms are defined under the American Recovery and Reinvestment Act of 2009 and regulations that may be promulgated thereunder.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements set forth below, and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, and wishing to be legally bound hereby, the Parties hereto agree as follows:

1. DEFINITIONS

Authorized User means an individual authorized by a Participant under an HIE Participation Agreement to use the Exchange to access or provide Data for a Permitted Use.

CCD means the Continuity of Care Document. It is a structured electronic document exchange standard utilized for sharing patient information among Participants. It provides certain composite, pertinent information about patients based upon (i) Medicaid and Other Source Data, (ii) select data fields from Data obtained from Participants, and (iii) unique patient identifying information from the master patient index/record locator service developed and maintained by GOEHI. The CCD is presented in a format that can be shared between computer applications and can be viewed in a web browser or can be consumed by an electronic medical record. The CCD provides a snapshot in time of a core data set of the most relevant clinical, demographic, and administrative data for a specific patient and provides the means for a Participant to transmit pertinent Data about a patient to another Participant, supporting continuity of care.

Data means patient health information provided to the Exchange by a Participant. For purposes of the Agreement, Data means information described in Section 4 herein.

Data Exchange means electronically providing or accessing Data through the Exchange.

Data Provider means a Participant that submits Data to the Exchange for use by a Data Recipient.

Data Recipient means a Participant that uses the Exchange to obtain Data.

Effective Date means the latest date of a signature of a person with authority to bind a Party to the Agreement.

Exchange means the Kentucky Health Information Exchange (KHIE) the health information exchange provided by GOEHI. The Exchange provides connection options for the capability to exchange key clinical information among Participants.

GOEHI means the Governor's Office of Electronic Health Information or its successor as may be created by the Kentucky General Assembly.

GOEHI's Services mean the information sharing and software described in Section 2 and Section 7 of the Agreement, respectively, provided by GOEHI.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, Title XII of the American Recovery and Reinvestment Act of 2009 (the "HITECH Act") and the Genetic Information Nondiscrimination Act of 2008 ("GINA"), and the regulations promulgated thereunder at 45 CFR Parts 160 and 164, each as may be amended from time to time.

HIPAA Privacy Rule means the regulations promulgated at 45 CFR Parts 160 and 164, as may be amended from time to time.

HIPAA Security Rule means the regulations promulgated at 45 CFR Parts 160, 162 and 164, as may be amended from time to time.

Medicaid and Other Source Data means information related to a patient provided to the Kentucky Health Information Exchange by the Department for Medicaid Services, Department for Public Health, other

agencies of the Cabinet for Health and Family Services, and third party payors, including but not limited to laboratory data from the Department for Public Health State Laboratory.

Operations shall have the definition assigned to Health Care Operations under HIPAA as limited by 45 CFR § 164.506(c)(iv).

Participant means a Health Care Provider who is also a Covered Entity as defined by HIPAA or the Kentucky Department for Medicaid Services or the Kentucky State Laboratory, Division of Laboratory Services, that has entered into an HIE Participation Agreement that has not been terminated, including the Participant named as a Party to the Agreement.

Participant Type means the category of Participants to which a particular Participant is assigned based upon that Participant's connection. A Participant's category may be Platinum, Gold, Silver or Edge Server or all the categories that apply.

Payment shall have the meaning set forth at 45 CFR § 164.501 of the HIPAA Regulations.

Permitted Use means use:

- (a) By health care providers:
 - (i) For Treatment, Payment and/or Operations such that patient authorization is not required under HIPAA; and
 - (ii) To facilitate the implementation of "meaningful use" criteria as required under the American Recovery and Reinvestment Act of 2009 and its related federal regulations, as permitted by HIPAA; and
- (b) By the Department for Medicaid Services:
 - (i) For Treatment and Payment for Medicaid patients and/or Operations such that patient authorization is not required under HIPAA, limited to functions related to case management, care coordination, and quality improvement activities; and
 - (ii) To facilitate the implementation of "meaningful use" criteria as required under the American Recovery and Reinvestment Act of 2009 and its related federal regulations, as permitted by HIPAA.
- (c) By the Kentucky State Laboratory, Division of Laboratory Services:

- (i) For Treatment and Payment for patients and/or Operations such that patient authorization is not required under HIPAA, limited to functions related to case management, care coordination, and quality improvement activities for the Kentucky newborn screening program as authorized in KRS 214.155 and cited as the James William Lazzaro and Madison Leigh Heflin Newborn Screening Act; and
- (ii) To facilitate the implementation of “meaningful use” criteria as required under the American Recovery and Reinvestment Act of 2009 and its related federal regulations, as permitted by HIPAA.

Proprietary and Confidential Party Information means proprietary or confidential materials or information of a Party or any contractor or subcontractor of a Party, such as those listed in Section 2.1(a) and those engaged by Participants to assist with connectivity and to provide support services, in any medium or format that is labeled as proprietary and/or confidential. Proprietary and Confidential Party Information includes, but is not limited to: (i) proprietary or confidential designs, drawings, procedures, trade secrets, processes, specifications, source code, exchange architecture, processes and security measures, research and development, including, but not limited to, research protocols and findings, passwords and identifiers, new products and marketing plans; (ii) proprietary financial and business information; and (iii) proprietary or confidential information or reports provided pursuant to this Agreement. Notwithstanding any label to the contrary, Proprietary and Confidential Party Information does not include: (a) Data content; (b) any information that is or becomes known to the public through no fault of a receiving Party; (c) any information that is learned by a receiving Party from a third party entitled to disclose it; (d) any information that is already known to a receiving Party before receipt from a Party as documented by receiving Party’s written records; (e) any information that is required to be disclosed by law or (f) any information that is independently developed by receiving Party without reference to, reliance on, or use of, Proprietary and Confidential Party Information. Data content is excluded from the definition of Proprietary and Confidential Party Information because other provisions of the Participation Agreement address the appropriate protections for this Data.

Treatment shall have the meaning set forth at 45 C.F.R. § 164.501 of the HIPAA Regulations.

Other capitalized terms used in the Agreement but not defined in the Agreement shall have the definitions assigned to such terms under HIPAA.

2. GOEHI OBLIGATIONS

2.1. Services Provided by GOEHI.

- (a) Exchange Operation. GOEHI will maintain and operate the Exchange. GOEHI has entered into a contract with ACS State Healthcare, LLC (“ACS”), and may contract with other contractors to maintain and operate the Exchange or to provide support services. ACS or any other contractor of GOEHI may contract with other subcontractors to maintain and operate the Exchange or to provide support services. GOEHI will require that its subcontractors comply with the applicable terms and conditions of the Agreement.

- (b) Services. GOEHI shall provide a standards-based CCD interface using web services to support Data Exchange with Participants. GOEHI shall be responsible for building the interfaces to the Participant on the Exchange side and shall collaborate with Participants to develop the interfaces required on the Participants' side. More advanced Data Exchange with the Exchange may be developed in collaboration among the Participants, their connection vendors, and GOEHI including Data from admission/discharge/transfer (ADT) systems, laboratory systems, diagnostic imaging systems (TCP/IP DICOM messaging), scanned documents (HL7 MDM T02 messaging), medication histories, allergies, and other interfaces required to support Data Exchange.
- (c) Access to Exchange for Permitted Use. GOEHI will make the Exchange available to Participants for Permitted Uses, including: (i) Data Recipients that may access Data through the Exchange; and (ii) Data Providers that provide Data for access by Participants through the Exchange. GOEHI may establish arrangements with other health information exchanges to allow Participants access to additional Data for a Permitted Use. GOEHI will require contractually that the users of such other health information exchanges which are permitted to access Data from Participants will limit access to Permitted Use only and will use its best efforts to enforce such contractual requirements. Any change to a Permitted Use must be documented in an Addendum signed by the Parties.
- (d) Exchange Availability. GOEHI will make all reasonable efforts to make the Exchange available to Participants 24 hours a day, 7 days a week; however, the Exchange availability may be temporarily suspended for maintenance or unscheduled interruptions. GOEHI will use its best efforts to provide reasonable advance notice of any such suspension or interruptions of the Exchange availability and to restore the Exchange availability.

2.2. GOEHI Records; Use of Data.

- (a) GOEHI Records. GOEHI will maintain records of the date, time and records accessed by a Participant through the Exchange as set forth in its Policies and Standards. GOEHI may also maintain a master patient index, a record locator service and Medicaid and Other Source data as part of the Exchange for the benefit of the Participants. Except as provided above, GOEHI will not maintain, and will not be responsible for either maintaining records of the content of any Data Exchange between Participants or inspecting the content of Data.
- (b) GOEHI Use and Disclosure of Information. GOEHI will not disclose Data or Data Exchange Information to any non-Participant third parties except as: (i) provided by the Agreement; (ii) directed in writing by the originating Participant; or (iii) required by order of any court with appropriate jurisdiction over GOEHI. GOEHI may disclose Medicaid and Other Source Data as permitted under applicable law. GOEHI may access Data and Data Exchange Information only for the operation of the Exchange, including collecting Medicaid or Other Source Data for the master patient

index/record locator service, testing, verifying performance, and providing success measurements to the federal government for the Medicaid Transformation Grant or any other federal grant awarded to any agency within the Cabinet for Health and Family Services of the Commonwealth of Kentucky and funded by the American Recovery and Reinvestment Act. GOEHI may use Data that has been de-identified pursuant to 45 CFR §164.514 to measure the success of the Medicaid Transformation Grant or any other federal grant awarded to the any agency of the Cabinet of Health and Family of the Commonwealth of Kentucky funded by the American Recovery and Reinvestment Act, if the use is compliant with HIPAA.

2.3. Safeguards. GOEHI shall safeguard the confidentiality of all Data obtained by GOEHI from Participant in connection with the Agreement, and in accordance with applicable state and federal laws including HIPAA. The Parties have entered into a Business Associate Agreement that is incorporated and made a part of the Agreement, whether attached or not.

2.4. Policies and Standards. GOEHI will establish policies and standards (respectively, “Policies and Standards”) that are consistent with the Agreement and will govern GOEHI’s and Participant’s use of the Exchange. It is the intention of the Parties that the development of the Policies and Standards will be through the KHIE Coordinating Council and its committees. The six initial pilot Participants will be allowed to participate as members of such committees. GOEHI will make these Policies and Standards available to Participant through the website of the Cabinet for Health and Family Services. These Policies and Standards will govern the use, submission, transfer, access, privacy and security of Data. These Policies and Standards, however, shall not alter the relative rights and obligations of the Parties under the Agreement.

(a) Changes to Policies and Standards. GOEHI may change or amend the Policies and Standards from time to time at its discretion but not inconsistent with the terms and conditions of the Agreement and will notify the Participant of proposed and final changes and will afford Participant an opportunity to comment on such proposed and final changes. GOEHI will provide Participants notice of such changes to Policies and Standards by electronic mail. Any changes will be effective thirty (30) days following adoption by GOEHI unless GOEHI determines that an earlier effective date is required to address a legal requirement, a concern relating to the privacy or security of Data or an emergency situation. GOEHI also may postpone the effective date of a change if GOEHI determines, in its sole discretion, that additional implementation time is required. Except as set forth in the Agreement, Participant will have no ownership or other property rights in the Policies and Standards or other materials or services provided by GOEHI.

(b) Security. GOEHI will adopt Policies and Standards that are reasonable, appropriate and consistent with the Agreement and will operate the Exchange in accordance with such Policies and Standards to provide that all Data Exchanges are authorized, and to protect Data from improper access, tampering or unauthorized disclosure. Such Policies and Standards will include administrative procedures, physical security measures, and technical security services that are reasonably necessary to secure the Data. GOEHI and Participant will comply with the security Policies and Standards established by GOEHI. GOEHI will maintain sufficient safeguards and procedures, in compliance with HIPAA, to maintain the security and privacy of Data that is provided or accessed through Data Exchanges through the Exchange.

(c) Investigations. GOEHI will adopt Policies and Standards for the investigation and resolution of privacy and security incidents or other concerns relating to compliance with the Agreement. GOEHI will notify Participant in writing of any compliance concerns related to Participant's use of the Exchange, and Participant will cooperate with GOEHI in its investigation of any compliance concerns or corrective action. Notwithstanding the Policies and Standards or anything in this Agreement, the Parties' reserve their rights to investigate, handle and resolve personnel and medical staff issues in their sole discretion and to maintain confidentiality of such matters.

3. PARTICIPANT OBLIGATIONS

3.1. Limitation of Section 3. The obligations of this Section 3 apply to Participant if either the "Both" or the "Data Recipient" line is checked on the Participant Election Form set forth on Exhibit B. These obligations do not apply to Participants who have only checked the "Data Provider" line on the Participant Election Form.

3.2. Participant Election. Participant shall complete the Participant Election Form set forth on Exhibit B and return it to GOEHI before approval to access the Exchange may be granted.

3.3. Data Exchange. By engaging in Data Exchange, Participant agrees that its participation in any Data Exchange, and use of the Exchange by Participant and its Authorized Users, will comply with the terms of the Agreement and applicable laws and regulations.

3.4. Permitted Use. Participant and its Authorized Users will use the Exchange only for a Permitted Use. Participant and its Authorized Users will comply with the Agreement and all applicable laws and regulations governing the privacy and security of Data received through the Exchange. Data obtained by Participant through the Exchange may become part of Patient's medical record. If Participant includes Data obtained through a Data Exchange in Patient's medical record, Participant and Authorized User may use such Data only for those purposes permitted by law. Participant will decide in its discretion whether to use the Exchange, and to what extent.

No Participant or Authorized User may use the Exchange or Data received from the Exchange to perform comparative studies/analysis or data aggregation without written consent from the Participant owning such Data, unless such use is a "Permitted Use."

3.5. Authorized Users. Participant will identify and authenticate its Authorized Users, in accordance with the Policies and Standards, who may use the Exchange for Permitted Use on behalf of Participant. Authorized Users will include only those individuals who require access to the Exchange to facilitate Participant's use of the Data for a Permitted Use. Participant shall require its Authorized Users to comply with the terms and conditions of the Agreement and applicable laws and regulations.

3.6. System Operations.

(a) Systems Necessary to Participate in Exchange. Participant, at its own expense, will provide and maintain the equipment, software, services and testing necessary to use the Exchange as set forth in Exhibit A, except for such software expressly provided by GOEHI pursuant to Section 6 of the Agreement.

(b) Documentation of Information for Patient Treatment; Record Retention, Storage and Backup. As Participant deems necessary, Participant, at its own expense, will maintain records of Data accessed through the Exchange and used by Participant for Treatment. Participant will determine the form for such records, which may include incorporation of Data into patients' medical records electronically, by hard copy or by other form of summary, notation or documentation.

(c) Privacy, Security and Accuracy. Participant will maintain sufficient safeguards and procedures, in compliance with HIPAA, to maintain the security and privacy of Data.

4. DATA PROVIDER OBLIGATIONS

4.1. Limitation of Section 4. The obligations of this Section 4 apply to Participant if either the "Both" or the "Data Provider" line is checked on the Participant Election Form set forth on Exhibit B. These obligations do not apply to Participants who have only checked the "Data Recipient" line on the Participant Election Form.

4.2. Participant Election. Participant shall complete the Participant Election Form set forth on Exhibit B and return it to GOEHI before approval to access the Exchange may be granted.

4.3. Data Exchange and Data Submission. By engaging in Data Exchange, Participant agrees that: (a) its participation in any Data Exchange will comply with the terms of the Agreement and applicable laws and regulations; and (b) the Data provided by Participant can be related to and identified with source records maintained by Participant. Participant will make Data available for the Exchange in accordance with the scope, format and specification set forth in Exhibit A.

4.4. Permitted Use. Participant and its Authorized Users will use the Exchange to provide Data only for a Permitted Use. Participant will and will require its Authorized Users to comply with the Agreement and all applicable laws and regulations governing the privacy and security of Data received through the Exchange. Participant and GOEHI acknowledge that Participant will make Data available for access through the Exchange only for a Permitted Use.

4.5. System Operations.

(a) Systems Necessary to Participate in Exchange. Participant, at its own expense, will provide and maintain the equipment, software, services and testing necessary to participate in the Exchange as set forth in Exhibit A, except for such software expressly provided by GOEHI pursuant to Section 6.

(b) Record Retention, Storage and Backup. Participant, at its own expense, will maintain Data backup and retention to maintain records of Data submitted to the Exchange.

(c) Privacy, Security and Accuracy. Participant will maintain sufficient safeguards and procedures, in compliance with HIPAA, to maintain the security and privacy of Data.

4.6. Data Provided. Participant, with the exception of Kentucky State Laboratory, agrees to make available the following Data to the Exchange to the extent technologically feasible and to the extent created and maintained by Participant:

(a) All of its hospital-specific inpatient data, including subsequent corrections or additions, as defined and required by the KHIE Participant Connectivity Guide, as amended from time to time;

(b) All of its outpatient surgical data, including subsequent corrections or additions, as described in the KHIE Participant Connectivity Guide, as amended from time to time;

(c) All of its emergency room Data;

(d) All ambulatory care Data;

The Kentucky State Laboratory, Division of Laboratory Services, agrees to make available all data referenced in EXHIBIT D.

5. NOTIFICATION OF PARTICIPANT'S BREACH OR VIOLATION

5.1 If Participant knows of an occurrence, activity or practice that constitutes a material breach or violation of the Agreement, Participant agrees to notify GOEHI within five (5) business days of determining that such occurrence, activity or practice constitutes a material breach or violation of this Agreement and must take reasonable steps to cure the material breach or end the violation. If the steps are unsuccessful, GOEHI may terminate the Agreement.

6. SOFTWARE LICENSE

6.1. License. GOEHI grants to Participant for the term of the Agreement a royalty-free, non-exclusive, nontransferable, non-assignable, non-sub-licensable, and limited right to use any software identified by GOEHI in its technical operation Standards for the sole purpose of participating in the Exchange under the terms and conditions of the Agreement. THE SOFTWARE SHALL NOT BE USED FOR ANY OTHER PURPOSE WHATSOEVER, AND SHALL NOT OTHERWISE BE COPIED OR INCORPORATED INTO ANY OTHER COMPUTER PROGRAM, HARDWARE, FIRMWARE, OR PRODUCT. THE SOFTWARE IS LICENSED "AS IS" AND GOEHI DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR TITLE. Participant acknowledges that the software may have been licensed to GOEHI by third parties, and that the license granted under the Agreement is subject to the extent permitted by law to GOEHI's grant of license from such third parties. As additional software is developed by or for GOEHI for the Exchange, it shall become subject to the Agreement and a part of this license upon written notice to Participant. This Section 6 applies only to software that is installed on hardware owned or leased by Participant or otherwise provided to Participant by GOEHI to use the Exchange.

7. PROPRIETARY PROVISIONS

During the term of the Agreement, each Party may have access to Proprietary and Confidential Party Information. To the extent that a Party receives Proprietary and Confidential Party Information, each party agrees to the following.

7.1. **Non-disclosure.** The Parties will hold Proprietary and Confidential Party Information in strict confidence, which includes not making the Proprietary and Confidential Party Information available for any purpose other than as specified in the Agreement and taking reasonable steps to ensure that the Proprietary and Confidential Party Information is not disclosed or distributed by employees, agents or contractors or consultants (who will have access to the same only on a “need to know” basis) to third parties in violation of the Agreement.

However, nothing in this Section 7.1 shall prohibit or be deemed to prohibit a Party from disclosing any Proprietary and Confidential Party Information (or any other information the disclosure of which is otherwise prohibited hereunder) to the extent that such Party becomes legally compelled to make such disclosure by reason of a subpoena or order of court, administrative agency or other governmental body of competent jurisdiction or as required by the Kentucky Open Records Act, and such disclosures are expressly permitted hereunder; provided, however, that a Party that has been requested or becomes legally compelled to make a disclosure otherwise prohibited hereunder by reason of a subpoena or order of a court, administrative agency or other governmental body of competent jurisdiction shall provide the other Party with notice thereof within five (5) calendar days, or if sooner, at least three (3) business days before such disclosure will be made so that the other Party may seek a protective order or other appropriate remedy. In no event shall a Party be deemed to be liable hereunder for compliance with any such subpoena or order of any court, administrative agency or other governmental body of competent jurisdiction or with the Kentucky Open Records Act.

7.2. **Damages.** In no event shall GOEHI and their respective officers, directors, employees, successors and assigns be responsible for any indirect, special, incidental, consequential or similar damages to Participant or any other person or entity resulting from Participant's use of the Exchange or Data obtained from the Exchange.

8. TERM AND TERMINATION

8.1. **Term.** The Agreement shall become effective on the Effective Date and shall continue until terminated by a Party as allowed by this Section of the Agreement.

8.2. **Termination.** The Agreement shall continue in effect and be automatically renewed annually until terminated with or without cause by written notice by a Party.

8.3. **Notice.** Any notice required under this Section 8 of the Agreement shall be given in accordance with Section 13.10 of the Agreement and Section 3.0 and 4.0 of the Business Associate Agreement attached hereto as Exhibit C and incorporated by reference.

9. WARRANTIES

9.1 **No Warranties – GOEHI.** GOEHI will use its best efforts to correctly transmit Data Exchanges between Participants on a timely basis. GOEHI MAKES NO REPRESENTATION OR WARRANTY THAT THE DATA DELIVERED TO THE DATA RECIPIENT WILL BE CORRECT OR COMPLETE. GOEHI MAKES NO WARRANTY OR REPRESENTATION REGARDING THE ACCURACY OR RELIABILITY OF ANY INFORMATION TECHNOLOGY SYSTEM USED FOR THE EXCHANGE. **GOEHI DISCLAIMS ALL WARRANTIES REGARDING ANY PRODUCT, SERVICES, OR RESOURCES PROVIDED BY IT, OR DATA EXCHANGES TRANSMITTED, PURSUANT TO THE**

AGREEMENT INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.

9.2 No Warranties - Participant. Participant expressly disclaims any and all warranties regarding the patient data of Participant through the Exchange, including, without limitation, any and all warranties of accuracy, completeness, fitness for a particular use and any other express or implied warranties. Participant acknowledges and agrees that any data accessed by Participant or its Authorized Users is provided on an “as-is” and “where-is” basis, and GOEHI, its contractors, subcontractors and Participant shall take all reasonable efforts necessary to inform Authorized Users of their responsibility to review, update and confirm the accuracy of any information accessed through the Exchange. Use of the Exchange is not a substitute for a health care provider’s standard practice or professional judgment. Any decision with respect to the appropriateness of diagnoses or treatments or the validity or reliability of information is the sole responsibility of the patient’s health care provider. Nothing in this subsection 9.2 is intended to limit Participant’s obligations under Section 3 or Section 4 of the Agreement.

10. LIMITATION OF LIABILITY

10.1. Limitation of Liability. Except as provided in Section 6.0 of the Business Associate Agreement, neither GOEHI nor Participant will be liable to the other or any other contractor or subcontractor of a Party, such as those listed in Section 2.1(a) and those engaged by Participant, for lost profits or lost Data, or any special, incidental, exemplary, indirect, consequential or punitive damages (including loss of use or lost profits) arising from any delay, omission or error in a Data Exchange or receipt of Data, or arising out of or in connection with the Agreement, whether such liability arises from any claim based upon contract, warrant, tort (including negligence), product liability or otherwise, and whether or not either party has been advised of the possibility of such loss or damage.

10.2. Not a Medical Service. The Exchange does not make clinical, medical or other decisions and is not a substitute for professional medical judgment applied by Participant or its Authorized Users. Participant and its Authorized Users are solely responsible for confirming the accuracy of all Data.

11. HIPAA COMPLIANCE

The Parties agree to comply with, and to cause their respective employees, subcontractors and agents to comply with, as appropriate, HIPAA, as well as other state and federal laws and regulations relating to the security, protection and privacy of individually identifiable health care information. GOEHI shall in good faith execute any and all agreements that Participant is required to have GOEHI execute in order that Participant may comply with HIPAA. In the event that either Party or its employees or agents fail to comply with this provision, the complying Party may immediately terminate the Agreement, in addition to seeking other remedies available to it at law or equity.

12. MISCELLANEOUS

12.1. Interpretation. Any ambiguity in the Agreement shall be resolved in favor of a meaning that permits the Parties to comply with HIPAA. Any inconsistency between the Agreement and the Business Associate Agreement shall be resolved in favor of the Business Associate Agreement.

12.2. No “Designated Record Set”. The Parties hereto agree that the Data submitted to the Exchange under the Agreement is not a “Designated Record Set” for purposes of individuals’ rights to access, inspect or amend “protected health information” about them under the HIPAA Privacy Rules.

12.3. No Third Party Beneficiaries. Nothing expressed or implied in the Agreement is intended to confer, nor shall anything herein confer, upon any person other than the Parties, their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

13. GENERAL PROVISIONS

13.1. Integration. Except as otherwise specifically stated herein, the Agreement sets forth the entire and only Agreement between GOEHI and the Participant relative to the Exchange. Any representations, promise, or condition, whether oral or written, not incorporated herein shall not be binding upon either Party.

13.2. Incorporation by Reference. All exhibits attached to the Agreement are incorporated by reference and made a part of the Agreement as if those exhibits were set forth in the text of the Agreement.

13.3. Relationship of Parties. Nothing contained in the Agreement shall constitute, or be construed to create, a partnership, joint venture, agency or any other relationship between the Parties other than that of independent contractors to the Agreement.

13.4. Assignment. In no event shall any party assign any of its rights, powers, duties, or obligations under the Agreement without receipt of the prior written consent of the other party, and any attempt to do so shall be void.

13.5. Severability. If any term, covenant, condition or provision hereof is illegal, or the application thereof to any person or in any circumstances shall, to any extent, be invalid or unenforceable, the remainder of the Agreement, or the application of such term, covenant, condition or provision to persons or in circumstances other than those with respect to which it is held invalid or unenforceable, shall not be affected thereby, and each term, covenant, condition and provision of the Agreement shall be valid and enforceable to the fullest extent of permitted by law.

13.6. Governing Law. The Agreement shall be construed and enforced in accordance with, and governed by, the laws of the Commonwealth of Kentucky.

13.7. Enforceability. The Agreement shall be enforceable only by the Parties hereto and their successors pursuant to an assignment which is not prohibited under the terms of the Agreement. In all other respects, the Agreement is not intended, nor shall it be construed, to create any other third party beneficiary rights.

13.8. Construction. If any language is stricken or deleted from the Agreement, such language shall be deemed never to have appeared herein and no other connotation shall be drawn therefrom. The paragraph headings used herein are for convenience only and shall not be used in the construction or interpretation of the Agreement.

13.9. Survival. The respective rights and obligations of the Parties under the provisions of Sections 2.3 (Safeguards), 3 (Participant Obligations), 4 (Data Provider Obligations), 7.1 (Non-disclosure), 9 (Warranties), 10.1 (Limitation of Liability), and 11 (HIPAA) shall survive the termination of this Agreement.

13.10. Notice. Any notice, offer, demand or communication required or permitted to be given under any provision of the Agreement shall be deemed to have been sufficiently given or served for all purposed if delivered personally to the party to whom the same is directed, or if sent by first class mail, postage and charges prepaid, addressed to the address of the Party set forth below.

To GOEHI:

SIGNATURE SECTION REMOVED

Except as otherwise expressly provided in the Agreement, any such notice shall be deemed to be given on the date ten (10) business days after the date on which the same is deposited in a regularly maintained receptacle for the deposit of United States mail, addressed as provided in the immediately preceding sentence. Either Party may change its address for purposes of the Agreement by giving the other Party notice thereof in the manner hereinbefore provided for the giving of notice.

13.11. Amendments. The Agreement cannot be changed, modified or discharged orally, but only with the written agreement of the Parties hereto.

13.12. Signing Authority. Each person signing the Agreement hereby represents that he or she is authorized to enter into the Agreement on behalf of the Party for which he or she is signing.

SIGNATURE SECTION REMOVED

EXHIBIT A CONNECTION CRITERIA

Silver

Functional Requirements:

- Ability to connect to the Exchange over a secure web service.
 - Ability to generate an HL7 v2.x QRY^T12 message and send over the web service, synchronous.
- Ability to receive an HL7 v2.x DOC^T12 message over a web service.
 - Ability to extract a CDA Document (CCD) from the Doc^T12
 - Ability to store a CCD Document
 - Ability to view a CCD Document in a Viewer

Optional:

- Ability to consume components of the CCD.

Gold

Gold involves being a Data Provider via the Exchange, and there are two ways to do this:

- Provide a document (Push) with Content via MDM^T02 to Participant owned or a hosted repository, as long as the repository can handle the query facility in a way that is compatible with the Exchange as described in this document.

- The Participant can develop the ability to do the reverse of “Silver” where the Participant hosts a service that can be queried (Pull) at any time by the Exchange via the QRY^T12 and return a DOC^T12 from the Exchange with the same WSDL that was developed for Silver.

Functional Requirements for Push:

- Ability to perform at Silver Level for KHIE Query
- Ability to provide an Encounter CCD to the Exchange following a patient visit (Physician – Clinic)
- Ability to provide Discharge CCD to the Exchange following patient discharge (Hospital)
- Ability to generate an HL7 v2.x MDM^T02 (Provide Document with Content) and MDM^T09 (Replace Document)
- Ability to include a CCD in the MDM message
- Exchange will Register Document in the XDS registry to allow sharing with other providers (internal MDM^T01 or ITI 41 messaging)
- The Participant will provide Repository for approved document types that may be shared among health care providers. This repository is not part of the Exchange.
- Exchange may include information in a consolidated CCD

Functional Requirements for Pull:

- Ability to perform at Silver Level for KHIE Query
- Ability to host a secure web service to be connected to the Exchange
- Ability to receive an HL7 v2.x QRY^T12 message and send an HL7 DOC^T12 message containing a CCD synchronously via the web service
- Ability to provide a CCD that contains data that is up to date

Platinum**Functional Requirements:**

- Ability to connect to the Exchange over a secure web service.
- Ability to utilize the KHIE Framework and Cross Enterprise Document Exchange (XDSb) to:
 - Register documents with the Exchange; and
 - Retrieve documents through the Exchange
- Ability to maintain a document repository accessible to the Exchange or utilize a Vendor-hosted repository that is independent from Exchange

Secondary:

- Ability to utilize the KHIE Framework and Cross Enterprise Document Sharing for Imaging (XDS I.b) to:
 - Register images and AVIs with the Exchange; and
 - Retrieve images through the Exchange
- Ability to maintain an accessible PACS image repository

Edge Server**Functional Requirements**

- Health care providers have the option to connect to the KHIE utilizing Edge Server technology with VPN tunnel connectivity. This process includes a standard series of HL7 transactions sent via the healthcare provider's Hospital Information System (HIS) to a secure Edge Server for storage and retrieval. From the Edge Server, the data is made available to the KHIE for exchange with other connected healthcare providers via inquiry, or the Virtual Health Record (VHR). The VHR is a web-based portal that may be distributed to those healthcare providers that require access to the patient's summary health data, but do not have the capability of sending or receiving a CCD.

**EXHIBIT B
PARTICIPANT ELECTION FORM**

Participants in the Exchange may submit or receive Data through the Exchange. A Participant may be both a Data Provider and a Data Recipient. Participant elects to be:

___ **BOTH.** Participant agrees to be a Data Provider and a Data Recipient.

___ **DATA PROVIDER.** Participant agrees to make and will make clinical Data available for access by Authorized Users for a Permitted Use.

___ **DATA RECIPIENT.** Participant agrees to participate in the Exchange to obtain health care information for a Permitted Use.

Participants in the Exchange must elect a Connection Criteria as described in Exhibit A. The Exchange requires the minimum system configuration for accessing and utilizing the Exchange as set forth in the Connection Criteria as described in Exhibit A. A Participant must elect one of the four Connection Criteria. Participant elects:

___ **SILVER.**

___ **GOLD.**

___ **PLATINUM**

___ **EDGE SERVER**

EXHIBIT C

RECITALS

SIGNATURE SECTION REMOVED

1.0. Definitions

1.1. **“Breach”** means the unauthorized acquisition, access, use, or disclosure of protected health information in a manner not permitted by the Privacy and Security Regulations, which compromises the security and privacy of protected health information, as more specifically defined in 45 C.F.R. 164.402.

1.2. **“Disclose”** and **“Disclosure”** mean, with respect to protected health information, the release, transfer, provision of access to, or divulging in any other manner of protected health information outside Business Associate’s internal operations.

1.3. **“Electronic Protected Health Information”** or **“Electronic PHI”** means protected health information that is transmitted by electronic media (as defined by the Privacy and Security Regulations) or is maintained in electronic media. Electronic PHI may be transmitted and maintained on devices such as cell phones, PDAs, text pagers, and USB static discs.

1.4. **“Protected Health Information”** or **“PHI”** means information, including demographic information, that (i) 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; (ii) identifies the individual (or for which there is a reasonable basis for believing that the information can be used to identify the individual); and (iii) is received by Business Associate from or on behalf of Covered Entity, or is created by Business Associate, or is made accessible to Business Associate by Covered Entity. PHI includes, without limitation, Electronic PHI.

1.5. “Secretary” means the Secretary of the U. S. Department of Health and Human Services or his or her designee.

1.6. “Services” means those activities, functions, or services that Business Associate provides for, or on behalf of Covered Entity.

1.7. “Unsecured PHI” means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through use of a technology or methodology specified in guidance by the Secretary.

1.8. “Use” or “Uses” mean, with respect to PHI, the sharing, employment, application, utilization, examination, or analysis of such PHI within Business Associate’s internal operations.

1.9. Terms used, but not otherwise defined in this Agreement shall have the same meaning as those terms in the Privacy and Security Regulations.

2.0. **Assurances by Business Associate Regarding PHI.** Business Associate warrants that it shall comply with relevant portions of the Privacy and Security Regulations as those regulations apply to business associates. More specifically, and insofar that Business Associate has access to, has been provided with, or will be creating PHI regarding Covered Entity’s patients, Business Associate warrants and agrees as follows:

2.1. Permitted Uses and Disclosures of PHI. Business Associate shall Use and Disclose PHI only in the amount minimally necessary to perform the Services for or on behalf of Covered Entity, including permitting the Use and Disclosure of PHI by and to “Participants” for “Permitted Use” (as such terms are defined in the Participation Agreement), provided that such Use or Disclosure would not violate the Privacy and Security Regulations if done by Covered Entity. Further, Business Associate:

2.1.1. shall Disclose PHI to Covered Entity upon request;

2.1.2. may as necessary for the proper management and administration of its business or to carry out its legal responsibilities, Use and Disclose PHI if:

2.1.2.1. the Disclosure is required by law, or

2.1.2.2. Business Associate obtains reasonable assurance from the person to whom the PHI is Disclosed that the PHI will be held confidentially and Used or further Disclosed only as required by law or for the purpose for which it was Disclosed to the person, and the person agrees to notify Business Associate of any instances of which the person is aware in which the confidentiality of the PHI has been breached.

Business Associate shall not Use or Disclose PHI for any other purpose.

2.2. Adequate Safeguards for PHI.

2.2.1. Business Associate shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of PHI in any manner other than permitted by this Agreement.

2.2.2. Business Associate shall implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic PHI that it creates, receives, maintains, or transmits on behalf of Covered Entity.

2.3. Reserved.

2.4. **Availability of Internal Practices, Books and Records to Government Agencies.** Business Associate agrees to make its internal practices, books, and records relating to the Use and Disclosure of PHI available to the Secretary for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations. Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.

2.5. **Access to PHI.** If Business Associate maintains PHI in a Designated Record Set, it shall make such PHI available to Covered Entity, or as directed by Covered Entity, to the individual identified as being entitled to access and copy that PHI, within the time frame and in a manner specified by Covered Entity.

2.6. **Amendment of PHI.** If Business Associate maintains PHI in a Designated Record Set, it shall make such PHI available to Covered Entity for the purpose of amendment and incorporating such amendments into PHI within the time and in such a manner specified by Covered Entity.

2.7. **Accounting of Disclosures.** Upon Covered Entity's request, Business Associate shall provide to Covered Entity an accounting of each Disclosure of PHI made by Business Associate or its employees, agents, representatives, or subcontractors.

2.7.1. Business Associate shall implement a process that allows for an accounting to be collected and maintained for any Disclosure of PHI for which Covered Entity is required to maintain. Business Associate shall include in the accounting: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the PHI; (c) a brief description of the PHI disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that requires an accounting under this section, Business Associate shall document the information specified in (a) through (d), above, and shall securely retain this documentation for six (6) years from the date of the Disclosure.

2.7.2. To the extent that Business Associate maintains PHI in an electronic health record, Business Associate shall maintain an accounting of Disclosure for treatment, payment, and health care operations purposes for three (3) years from the date of Disclosure. Notwithstanding anything to the contrary, this requirement shall become effective upon either of the following: (a) on or after January 1, 2014, if Business Associate acquired electronic health record before January 1, 2009; or (b) on or after

January 1, 2011 if Business Associate acquired an electronic health record after January 1, 2009, or such later date as determined by the Secretary.

2.8. Reporting Breaches of PHI.

2.8.1. Business Associate shall report to Covered Entity:

2.8.1.1. Each access, acquisition, Use, or Disclosure that is made by Business Associate, its employees, representatives, agents, or subcontractors but is not specifically permitted by this Agreement;

2.8.1.2. Any security incident of which it becomes aware. A security incident means the attempted, or successful unauthorized access, acquisition, Use, Disclosure, modification, or destruction of information, or interference with the system operation of an information system; or

2.8.1.3. A Breach of Unsecured PHI.

2.8.2. Business Associate's Notice to Covered Entity

2.8.2.1. Business Associate shall notify Covered Entity's Privacy Official by telephone call immediately following the first day on which Business Associate knows of such Breach.

2.8.2.2. Business Associate shall provide a full written report to Covered Entity's Privacy Official within five (5) business days of verbal notice. Business Associate shall include the following in the written report:

2.8.2.2.1. detailed information about the Breach, and immediate remedial action to stop the Breach; and

2.8.2.2.2. names and contact information of individuals whose PHI has been, or is reasonably believed to have been subject to the Breach.

3.0. Notice to Covered Entity. Any notice required under this Agreement to be given to Covered Entity shall be made to:

4.0. Notice to Business Associate. Any notice required under this Agreement to be given to Business Associate shall be made to:

SIGNATURE SECTION REMOVED

5.0. Mitigation and Cooperation. Business Associate shall mitigate, at Business Associate's sole cost and expense to the extent permitted by law, any harmful effect that is known to it for the Breach, or Use, or Disclosure of PHI in violation of this Agreement, as a result of the acts or omissions of Business Associate and/or its subcontractors, provided that Business Associate shall not be required to indemnify Covered Entity. Business Associate shall cooperate with Covered Entity in the notification of individuals as required and in the manner as set forth in the HITECH Act.

6.0. Remedies in Event of Breach. Business Associate recognizes that irreparable harm will result to Covered Entity in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of a breach, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of this Agreement. The remedies contained in this section shall be in addition to any action for damages and/or any other remedy Covered Entity may have for breach of any part of this Agreement.

7.0. Breach Pattern or Practice by Covered Entity. If Business Associate knows of an activity or practice of Covered Entity that constitutes a material breach or violation of Covered Entity's obligations under this Agreement, Business Associate must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, Business Associate must terminate the Services if feasible, or if termination is not feasible, report the activity to the Secretary. Within five (5) business days of discovery, Business Associate shall provide written notice to Covered Entity of any pattern of activity or practice of Covered Entity that Business Associate believes constitutes a material breach or violation of Covered Entity's obligations under this Agreement, and shall meet with Covered Entity to discuss and attempt to resolve the problem as one of the reasonable steps to cure or end the violation.

8.0. Breach Pattern or Practice by Business Associate. If Covered Entity knows of an activity or practice of Business Associate that constitutes a material breach or violation of Business Associate's obligations under this Agreement, Covered Entity must take reasonable steps to cure the breach or end the violation. If the steps are unsuccessful, Covered Entity must terminate the Business Associate's Services if feasible, or if termination is not feasible, report the activity to the Secretary. Within five (5) business days of discovery Covered Entity shall provide written notice to Business Associate of any pattern of activity or practice of Business Associate that Covered Entity believes constitutes a material breach or violation of Business Associate's obligations under this Agreement, and shall meet with Business Associate to discuss and attempt to resolve the problem as one of the reasonable steps to cure or end the violation.

9.0. Disposition of PHI Upon Termination or Expiration. Upon termination or expiration of this Agreement, Business Associate shall either return or destroy, in Covered Entity's sole discretion and in accordance with any instructions by Covered Entity, all PHI in the possession or control of Business Associate or its agents and subcontractors. However, if either return or destruction of PHI is not feasible, Business Associate may retain PHI provided that Business Associate (a) continues to comply with the provisions of this Agreement for as long as it retains PHI, and (b) limits further Uses and Disclosures of PHI to those purposes that make the return or destruction of PHI infeasible.

10.0. Document Retention. Business Associate shall maintain all documentation required by the Privacy and Security Regulations for a period of six (6) years.

11.0. Conflict. In the event there is a conflict between the language of this Agreement and the Services, the terms and conditions of this Agreement shall control.

12.0. No Third Party Beneficiaries. There are no third party beneficiaries to this Agreement.

13.0. Use of Subcontractors and Agents. Business Associate shall require each of its agents and subcontractors that receive PHI from Business Associate to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Agreement.

14.0. Term and Termination. The term of this Agreement shall be the same as the term of the underlying services agreement. In addition to and notwithstanding the termination provisions set forth in the underlying services agreement, both this Agreement and the agreement may be terminated by Covered Entity immediately and without penalty upon written notice by Covered Entity to Business Associate if Covered Entity determines, in its sole discretion, that Business Associate has violated any material term of this Agreement. The terms and conditions under this Agreement shall survive the termination of the underlying services agreement.

EXHIBIT D

**TO THE HEALTH INFORMATION EXCHANGE HOSPITAL PARTICIPATION AGREEMENT
BETWEEN THE GOVERNOR'S OFFICE OF ELECTRONIC HEALTH INFORMATION
AND
KENTUCKY STATE LABORATORY, DIVISION OF LABORATORY SERVICES**

KY Division of Laboratory Services List of Testing to be Shared through KHIE

VIROLOGY

Hepatitis B Surface Antigen
Hepatitis B Surface Antibody
Hepatitis B Core Antibody
Hepatitis A IgM

Varicella IgG (EIA)
Measles IgG (EIA)
Measles IgM (EIA)
Mumps IgG (EIA)
Herpes IgG
Cytomegalovirus IgG (EIA)
West Nile IgG (EIA)
West Nile IgM (EIA)
Herpes Shell Vial Testing
Herpes DFA slide testing
Norovirus PCR
Toxoplasmosis
VDRL Syphilis Screen
Rubella IgG (EIA)
Rubella IgM (EIA)
Rabies Panel
RCC – Rabies Cell Culture
Prenatal Profile
Viral Isolation Fluid- Non Influenza
Viral Isolation Swab- Non Influenza
Influenza PCR

BACTERIOLOGY

Salmonella grouping and typing
Shigella
Campylobacter
E. Coli
Miscellaneous Enteric Pathogens
VIB – Vibrio
Miscellaneous Bacteria Identification
Pinworm
Ova and Parasites
Neisseria meningitidis

MYCOBACTERIOLOGY

Tuberculosis (raw specimen)
Tuberculosis (culture isolate)

CLINICAL CHEMISTRY

Lipid Profile
Total Cholesterol
Fasting or Random Glucose
Glucose 1hr/ 50 gram
Glucose Postpartum Fasting
Glucose Tolerance Test (Prenatal)
Glucose Tolerance Test (Postpartum)

MOLECULAR

Chlamydia and Gonorrhoea

ENVIRONMENTAL

Water Bacteriology
Fluoride
Fluoride (Public Water System)
Fluoride (Supplement Program)

NEWBORN SCREENING

Division of Laboratory Services (DLS) screens infant blood spot specimens for over 40 different disorders.

SAMPLE