NC HIEA

Full Participation Agreement for Pharmacies for NC HealthConnex Access and Data Use

Version Date: September 20, 2024

North Carolina Health Information Exchange Authority Full Participation Agreement for Pharmacies for NC HealthConnex Access and Data Use

WITNESSETH:

WHEREAS, NC HIEA was created and enabled by the NC General Assembly through the Statewide Health Information Exchange Act (S.L. 2015-241) in order to assume operations of the previously authorized State health information exchange and associated network as the successor to the NC HIE, and for purposes enumerated therein, which the Parties acknowledge as public purposes of the State;

WHEREAS, NC HIEA is engaged in the oversight, administration and operation of a statewide electronic health information exchange network ("NC HealthConnex"), and in connection therewith makes available certain HIE Features (as defined herein) for use by Participants of NC HealthConnex. The Participants enter into this Agreement to enable their participation in health information exchange activities, as set forth below;

WHEREAS, Submitter is a pharmacy registered with the North Carolina Board of Pharmacy under Article 4A of Chapter 90 of the General Statutes;

WHEREAS, Participants in NC HealthConnex may voluntarily submit or receive data through NC HealthConnex; and a Participant may be both a data Submitter and a data Recipient, and the Participants desire to electronically Transact, on their own behalf or on behalf of their Authorized Users or Participating Entities, health information among Participants;

WHEREAS, notwithstanding the voluntary nature of NC HealthConnex under N.C.G.S. §90-414.2 and as a condition of receiving State funds, Health Care Providers are required by law to connect to NC HealthConnex and submit, through NC HealthConnex, demographic and clinical information or claims information pertaining to health care services rendered to Medicaid, State Health Plan for Teachers and State Employees, and other State-funded health care program beneficiaries and paid for with State-funded health care funds;

WHEREAS, the Participants are organizations that oversee and conduct, on their own behalf and on behalf of their Participating Entities and Authorized Users, electronic transactions or exchanges of health information among groups of persons or organizations; have the technical ability to electronically transact health information on their own behalf or on behalf of their Participating Entities and Authorized Users; have the organizational infrastructure and legal authority to comply with the obligations in this Agreement and to require their Participating Entities and Authorized Users to comply with applicable requirements in this Agreement;

WHEREAS, the relationship between the Participant and the individuals whose records are available within or through their respective Systems varies from Participant to Participant and, in some cases, there is no direct relationship;

WHEREAS, as a condition of Transacting information with other Participants, each Participant must enter into this Participation Agreement, and has agreed to do so by executing this Agreement;

NOW, THEREFORE, for and in consideration of the mutual covenants herein contained, the Participants hereto mutually agree as follows:

- 1. Cooperation. The Parties understand and acknowledge that numerous activities with respect to this Agreement shall likely involve each Party's employees, agents, and third-party contractors, vendors, or consultants. In seeking another Party's cooperation, each Party shall make all reasonable efforts to accommodate the other Party's schedules and reasonable operational concerns. A Party shall promptly report, in writing, to the other Party, any problems or issues that arise in working with the other Party's employees, agents, or subcontractors that threaten to delay or otherwise adversely impact a Party's ability to fulfill its responsibilities under this Agreement. In no case shall a Party be required to disclose PHI in violation of Applicable Law. This writing shall set forth in detail and with clarity the problems that the Party has identified. To the extent not legally prohibited, each Party shall:
 - 1.01. cooperate fully with the other Party and any such third parties with respect to such activities as they relate to this Agreement;
 - 1.02. provide such information to the other Party or such third parties as they may reasonably request for purposes of performing activities related to this Agreement;
 - 1.03. devote such time as may reasonably be requested by the other Party to review information, meet with, respond to, and advise the other Party with respect to activities as they relate to this Agreement;
 - 1.04. provide such reasonable assistance as may be requested by the other Party when performing activities as they relate to this Agreement; and
 - 1.05. subject to a Party's right to restrict or condition its cooperation or disclosure of information in the interest of preserving privileges in any foreseeable dispute or litigation or protecting a Party's Confidential Participant Information, provide information and assistance to NC HIEA or other Parties in the investigation of HIPAA Breaches, Security Breaches, or Disputes.
- 2. **Definitions.** For the purposes of this Agreement, the following terms shall have the meaning ascribed to them below. All defined terms are capitalized throughout this Agreement. Certain terms are defined by, or defined by reference, N.C.G.S. § 90-414.3 and shall have the meaning and intent herein as set forth therein. Such terms include: business associate, business associate contract, covered entity, department, disclose or disclosure, emergency medical condition, HIPAA, individual, NC Health Information Exchange Advisory Board, NC Health Information Exchange Authority, opt out, protected health information, public health purposes, research purposes and State CIO.
 - 2.01. **Applicable Law** shall mean all applicable statutes and regulations of North Carolina and of the state(s) or jurisdiction(s) in which the Participant operates, as well as all applicable United States federal statutes, regulations, standards and policy requirements.
 - 2.02. **Approved Third Parties** shall mean Business Associates, Covered Entities, agencies of the State of North Carolina, and other entities that have entered into HIPAA compliant data sharing agreements with NC HIEA to further the purposes outlined in N.C.G.S. § 90-414.2 et. seq. and other Applicable Law.
 - 2.03. **Authorization** shall have the meaning and include the requirements set forth at 45 C.F.R. § 164.508 of the HIPAA Regulations and include any similar but additional requirements under Applicable Law.
 - 2.04. **Authorized User** shall mean any person who has been authorized to Transact Message Content through the respective Participant's System in a manner defined by the respective Participant. "Authorized Users" may include, but are not limited to, Health Care Providers; Health Plans; and employees, contractors, or agents of a Participant. An Authorized User may act as either a Submitter, Recipient or both when Transacting Message Content.
 - 2.05. **Clinical Portal** shall mean the NC HealthConnex portal system made available to Participant, Participating Entities, and Authorized Users to use for Permitted Purposes.

- 2.06. Confidential Participant Information, for the purposes of this Agreement, shall mean proprietary or confidential materials or information of a Participant in any medium or format that Participant labels as such upon disclosure. Message Content, Pharmacy Data, and HIE Data are excluded from the definition of Confidential Participant Information because other provisions of this Agreement and the DURSA address the appropriate protections for Message Content and HIE Data. Notwithstanding any label to the contrary, Confidential Participant Information does not include Message Content; any information which is or becomes known publicly through no fault of a Receiving Party; is learned of by a Receiving Party from a third party entitled to disclose it; is already known to a Receiving Party before receipt from a Participant as documented by Receiving Party's written records; or, is independently developed by Receiving Party without reference to, reliance on, or use of, Participant's Confidential Participant Information. Confidential Participant Information includes the following types of information which are not subject to disclosure pursuant to the N.C. Public Records Act when in the possession or custody of the NC HIEA, but is not limited to:
 - a. a Party's designs, drawings, procedures, trade secrets as defined in N.C.G.S. §66-152 *et seq.*, processes, specifications, source code, System architecture, security measures, research and development, including, but not limited to, research protocols and findings, passwords and identifiers, new products, and marketing plans;
 - b. proprietary financial and business information of a Party; and
 - c. information or reports provided by a Party to a Receiving Party in the performance of this Agreement.

For purposes of this Section 2.06 and 16, Submitter's information shall include third party information deemed proprietary, or non-public, by Submitter or such third party.

- 2.07. **Data Use and Reciprocal Support Agreement or DURSA** shall mean the second restatement of the multiparty legal agreement that established a trust framework between the participants of the nationwide eHealth Exchange that was updated on August 13, 2019. NC HIEA will or has become a participant of the eHealth Exchange.
- 2.08. **Digital Credentials** shall mean a mechanism that enables Participants to electronically prove their identity in order to connect to NC HealthConnex, to submit Pharmacy Data or HIE Data to NC HIEA, and to Transact Message Content with other Participants.
- 2.09. **Direct Secure Messaging** shall mean the encrypted messaging service provided to Participants by the NC HIEA, a certified Health Information Service Provider, that allows Participants to communicate securely with other NC HealthConnex Participants or with other certified Direct Secure Message recipients.
- 2.10. **DirectTrust** means the collaborative non-profit association of health information technology and health care provider organizations to support secure, interoperable health information exchange via Direct Secure Message protocols.
- 2.11. **Dispute** shall mean any controversy, dispute, or disagreement arising out of or relating to this Agreement.
- 2.12. **Effective Date** shall mean the date on which the last of the following events occurs (i): the full execution of this Agreement by both the Parties, and (ii) the full execution of the Business Associate Agreement by the parties attached hereto as Attachment 5.
- 2.13. **eHealth Exchange** shall mean the nationwide health information network that allows participants to exchange data using an agreed upon set of national standards, services and policies developed by the

- Sequoia Project in coordination with the Office of National Coordinator within the U.S. Department of Health and Human Services.
- 2.14. **EHR Product** shall mean the electronic software system, products or services used by Participants related to electronic health records, medical practice management solutions, and/or prescription drug treatment, including claims data.
- 2.15. **Go Live Date** shall mean the date of completion of the Onboarding process.
- 2.16. **Health Care Operations** shall have the meaning set forth at 45 C.F.R. §164.501 of the HIPAA Regulations.
- 2.17. **Health Care Provider** shall have the meaning set forth at 45 C.F.R. §160.103 of the HIPAA Regulations. The Parties acknowledge that this definition encompasses pharmacies registered with the North Carolina Board of Pharmacy under Article 4A of Chapter 90 of the General Statutes.
- 2.18. **Health Information Service Provider or HISP** shall mean a company or other organization that will support one or more Participants by providing them with operational, technical, or health information exchange services.
- 2.19. **Health Plan** shall have the meaning set forth at 45 C.F.R. §160.103 of the HIPAA Regulations.
- 2.20. **HIE Data** shall mean the clinical and demographic data submitted to, exchanged, and stored by NC HIEA as required by N.C.G.S. §90-414.4 together with such other PHI or individually identifiable information as may be necessary or proper to achieve the purposes of the NC HIEA in N.C.S.L. 2015-241, N.C.S.L. 2015-264, and other Applicable Law.
- 2.21. **HIE Features** shall mean a set of technical features that Participants have the option of accessing or using for Permitted Purposes, and for such other purposes as permitted by Applicable Law. Current HIE Features are identified in Attachment 7 and are available on the NC HIEA website.
- 2.22. **HIE Operations** shall mean the obligations of NC HIEA pursuant to the Statewide Health Information Exchange Act, N.C.G.S. §§ 90-414.1 et seq., and as provided for in Section 10. HIE Operations include the following:
 - a. Facilitating exchanges and Transactions of Pharmacy Data, HIE Data, and Message Content with eligible Participants and Approved Third Parties for Permitted Purposes.
 - b. Processing or otherwise implementing Opt Out requests.
 - c. Performing patient identity or patient records maintenance.
 - d. Conducting or assisting in the performance of audits permitted or required by the NC HIEA Policies and Procedures, including the performance of audits of emergency access.
 - e. Evaluating the performance of or develop recommendations for improving the operation of NC HealthConnex.
 - f. Conducting technical system support and maintenance of NC HealthConnex, including circumstances where suspension or degradation of services is required to maintain or update the performance of the NC HealthConnex Resources. NC HIEA performs maintenance and upgrades on the third week of each month and as needed. Users may experience slower performance of or the inability to access affected HIE features during this period.
 - g. Engaging in any other activities as may be required to facilitate the operation of NC HealthConnex that are authorized by NC HIEA and are consistent with this Agreement and Applicable Law.
- 2.23. **HIPAA Breach** shall mean the unauthorized acquisition, access, disclosure, or use of Pharmacy Data, HIE Data, or Message Content while Transacting such Message Content, or Protected Health

Information while utilizing the NC HealthConnex Resources pursuant to this Agreement. The term "HIPAA Breach" does not include the following:

- a. any unintentional acquisition, access, disclosure, or use of Pharmacy Data, HIE Data, PHI, or Message Content by an employee or individual acting under the authority of a Participant or Authorized User if:
 - 1. such acquisition, access, disclosure, or use was made in good faith and within the course and scope of the employment or other professional relationship of such employee or individual, respectively, with the Participant or Authorized User; and
 - 2. such information is not further acquired, accessed, disclosed or used by such employee or individual; or
 - 3. any acquisition, access, disclosure or use of information contained in or available through the Participant's System where such acquisition, access, disclosure or use was not directly related to Transacting Message Content.
- b. Unauthorized disclosure of Participant Confidential Information.
- 2.24. **Individual** shall have the meaning set forth at 45 C.F.R. §160.103 of the HIPAA Regulations.
- 2.25. **Meaningful Use of Certified Electronic Health Record Technology or Meaningful Use** shall have the meaning assigned to it in the regulations promulgated by the U.S. Department of Health and Human Services under 42 USC §§1395w-4, -1395ww (the American Recovery and Reinvestment Act, Sections 4101 and 4102).
- 2.26. **Medicaid** shall mean the health insurance program for certain low-income and/or disabled individuals that is administered by the North Carolina Department of Health and Human Services.
- 2.27. Message shall mean an electronic transmission of Message Content Transacted between Participants and the State of North Carolina using NC HealthConnex. Messages are intended to include all types of electronic transactions as necessary or desired for the Permitted Purposes, including the data or records transmitted with those transactions.
- 2.28. **Message Content** shall mean that information contained within a Message or accompanying a Message. This information includes, but is not limited to, Protected Health Information (PHI), deidentified data (as defined in the HIPAA Regulations at 45 C.F.R. § 164.514), individually identifiable information, pseudonymized data, metadata, Digital Credentials, and schema associated actually or logically with PHI. Message Content does not include Pharmacy Data submitted by Participant to NC HIEA as required by N.C.G.S. § 90-414.4(b).
- 2.29. NC HealthConnex Resources shall mean software, utilities and automated tools, if any, made available for use by NC HIEA or a third party in connection with the Transaction of Message Content. This includes access to NC HealthConnex via the Clinical Portal, interfaces between Participant's EHR Product and NC HealthConnex, the HIE Features, and any other NC HealthConnex Resources identified by NC HIEA.
- 2.30. NC HIEA Policies and Procedures shall mean the policies and procedures, including the Privacy and Security Policies and User Access Policies, adopted by NC HIEA that describe (i) management, operation and maintenance of NC HealthConnex; (ii) qualifications, requirements and activities of Participants and Authorized Users when accessing the NC HealthConnex Resources or Transacting Message Content with other Participants; and (iii) support of the Participants who wish to Transact Message Content with other Participants. The NC HIEA Policies and Procedures are amended from time to time in accordance with Section 9.03; they are available on the NC HIEA website (https://hiea.nc.gov/providers/nc-hiea-policies).

- 2.31. **Notice or Notification** shall mean a written communication, unless otherwise specified in this Agreement, sent to the appropriate Participant's representative at the address listed in Attachment 1 or NC HIEA in accordance with Section 22.
- 2.32. **Office of the National Coordinator or ONC** shall mean the Office of the National Coordinator for Health Information Technology within the U.S. Department of Health and Human Services.
- 2.33. **Onboarding** shall mean the process of establishing and implementing the required credentials for Participants to access NC HealthConnex Resources, and building an active connection between Participant and NC HealthConnex through secure electronic data submission that allows Participant to submit Pharmacy Data to the NC HIEA pursuant to N.C.G.S. §90-414.4(b).
- 2.34. **Onboarding and Technical Specifications** shall mean the Onboarding and technical process and specifications for connecting to NC HealthConnex, for submitting Pharmacy Data to NC HealthConnex as required by Applicable Law, as well as any implementation guidance and other technical materials and resources approved by NC HIEA.
- 2.35. **Participant** shall mean any organization that (i) meets the requirements for participation as contained in N.C.G.S.§ 90-414.7 *et seq.*; (ii) is provided with Digital Credentials; and (iii) is a signatory to this Agreement. Participants may act as a Submitter, Recipient or both when Transacting Message Content.
- 2.36. **Participant Account Administrator** means the staff member(s) employed by Participant or Participating Entities who will be authorized to assign user credentials to Authorized Users within the Participant's or Participating Entity's Workforce. The Participant Account Administrator will also be the main contact person who will receive communication from NC HIEA and who will coordinate the collaboration between NC HIEA's technology vendor and the Participant's technical services staff.
- 2.37. Participating Entities shall include (i) entities that a Participant has control over, (ii) entities that are under common control with Participant, and/or (iii) entities that share information systems with Participant, and for whom Participant will submit or cause to submit Pharmacy Data under this Agreement. Participating Entities may elect to submit Pharmacy Data or Transact Messages through NC HealthConnex under a single Participant or as multiple separate Participants. A Participating Entity of a Participant may also be a natural person or business entity with whom the Participant has a direct or indirect business or employment relationship, including any person or entity provided a license or right to access and use any of a Participant's EHR Product, software and/or services. However, if Participant does not intend to sign this Agreement on behalf of such natural persons or business entities, those persons or entities should sign a separate Agreement.
- 2.38. **Payment** shall have the meaning set forth at 45 C.F.R. §164.501 of the HIPAA Regulations.

2.39. **Permitted Purposes**

- a. As to Participants, Permitted Purposes shall mean one of the following reasons for which Participants may legitimately exchange Pharmacy and/or HIE Data, Transact Message Content, or otherwise use, access, or disclose Pharmacy and/or HIE Data:
 - 1. Treatment of the Individual;
 - 2. Payment activities, provided that the Participant has an established Treatment relationship with the Individual and that the use or Disclosure otherwise complies with the requirements of HIPAA and is otherwise permitted by Applicable Law;
 - 3. Health Care Operations of the Participant;

- 4. Public health activities and reporting as permitted by Applicable Law, including N.C.G.S. §90-414.5, Chapter 130A and the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e);
- 5. Any purpose to demonstrate Meaningful Use of Certified Electronic Health Record Technology by the (i) Submitter, (ii) Recipient or (iii) Covered Entity on whose behalf the Submitter or the Recipient may properly Transact Message Content under this Agreement, provided that the purpose is not otherwise described in subsections (a)(1) through (4) of this definition and the purpose is permitted by Applicable Law, including but not limited to the HIPAA regulations;
- 6. Research purposes as permitted by Applicable Law and the NC HIEA Policies (please note that is not a Permitted Purpose for Transacting Message Content through the eHealth Exchange);
- 7. To carry out Benefits Determinations; and
- 8. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual's personal representative as described in 45 C.F.R. §164.502(g) of the HIPAA Regulations.
- b. As to NC HIEA, Permitted Purposes shall mean one of the following reasons for which NC HIEA may legitimately exchange Pharmacy Data and/or HIE Data, Transact Message Content, or otherwise use, access, or disclose Pharmacy Data and/or HIE Data:
 - 1. HIE Operations;
 - 2. Public health activities and reporting as permitted by Applicable Law, including N.C.G.S. §90-414.1 *et seq.*, Chapter 130A and the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e);
 - 3. Health Care Operations;
 - 4. Benefits Determinations for Individuals who apply for or do receive services from State funded programs;
 - 5. Activities to support data aggregation and analytics as set forth in 45 § C.F.R. 164.504(e), N.C.S.L. 2015-264 Section 86.5.(a), and other Applicable Law;
 - 6. Research purposes as permitted by Applicable Law and the NC HIEA Policies and Procedures; and
 - 7. Activities required by Applicable Law; and
 - 8. Support of the Permitted Purposes of Participants and Approved Third Parties.
- c. As to Approved Third Parties, Permitted Purposes shall mean one of the following reasons for which Approved Third Parties may legitimately exchange Pharmacy Data and/or HIE Data, Transact Message Content, or otherwise use, access, or disclose Pharmacy Data and/or HIE Data:
 - 1. If Transacted through the eHealth Exchange or another nationwide or regional network, for all Permitted Purposes listed in subsection (a) of this Section with the exception of any purpose excluded by the relevant nationwide or regional network governance body or agreement (e.g., See Attachment 9);
 - 2. Public health activities and reporting as permitted by Applicable Law, including N.C.G.S. §90-414.5, Chapter 130A and the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e):
 - 3. Research purposes as permitted by Applicable Law and the NC HIEA Policies and Procedures; and

- 4. Activities required or permitted by Applicable Law, including N.C.G.S §§ 90-414.4(a) and 90-414.2.
- d. Pursuant to N.C.G.S. § 90-414.6, no entity may use, disclose, or access Pharmacy Data and/or HIE Data for commercial purposes.
- 2.40. **Primary Provider User Guide** shall mean the user guide published by NC HIEA that provides education and guidance to Participants, Participating Entities, and Authorized Users on the operation of NC HealthConnex and the NC HealthConnex Clinical Portal.
- 2.41. **Privacy and Security Policies** shall mean the HIPAA compliant policies and procedures developed and adopted by each Party that govern the privacy and security of access to NC HealthConnex and the NC HealthConnex Resources.
- 2.42. **Receiving Party** shall mean a Party or Participant that receives Confidential Participant Information in any capacity from a Recipient.
- 2.43. **Recipient** shall mean the Participant(s) or Authorized User(s) that receives Message Content through a Message from a Submitter for a Permitted Purpose. For purposes of illustration only, Recipients include, but are not limited to, Participants, Participating Entities, or Authorized Users who receive queries, responses, subscriptions, publications or unsolicited Messages.
- 2.44. **Security Breach** shall have the meaning set forth at N.C.G.S. §75-61; i.e. An incident of unauthorized access to and acquisition of unencrypted and unredacted records or data containing personal information where illegal use of the personal information has occurred or is reasonably likely to occur or that creates a material risk of harm to a consumer. Any incident of unauthorized access to and acquisition of encrypted records or data containing personal information along with the confidential process or key shall constitute a Security Breach. Good faith acquisition of personal information by an employee or agent of the business for a legitimate purpose is not a Security Breach, provided that the personal information is not used for a purpose other than a lawful purpose of the business and is not subject to further unauthorized disclosure. For the purposes of this Agreement, only Security Breaches that involve personal information accessed, used, or disclosed through the NC HealthConnex System will require compliance with the relevant provisions in this Agreement, in addition to Applicable Law.
- 2.45. **State** shall mean the State of North Carolina.
- 2.46. State Health Plan for Teachers and State Employees or State Health Plan shall mean the health insurance plan provided for employees of the State of North Carolina.
- 2.47. **Submitter** shall mean the Participant(s) or Authorized User(s) who submits Message Content through a Message to a Recipient for a Permitted Purpose. For purposes of illustration only, Submitters include, but are not limited to, Participants or Authorized Users who push Messages with Message Content, send Messages seeking Message Content, send Messages in response to a request, send subscription Messages, or publish Messages with Message Content in response to subscription Messages.
- 2.48. **System** shall mean software, portal, platform, or other electronic medium controlled by a Participant through which the Participant conducts its health information exchange related activities. For purposes of this definition, it shall not matter whether the Participant controls the software, portal, platform, or medium through ownership, lease, license, or otherwise.
- 2.49. **Targeted Data Standards** shall mean standards adopted by the NC HIEA concerning Pharmacy Data that identify t the required data elements, fields, and data feeds that must be submitted to NC HIEA through NC HealthConnex in order for Participant to comply with N.C.G.S. § 90-414.4(b) as set forth

- on Attachment 3. The Parties acknowledge the Targeted Data Standards conform to pharmacy industry standardized formats.
- 2.50. **Test or Testing** shall mean the tests and demonstrations of a Participant's System and processes used for interoperable health information exchange, to assess conformity with the Onboarding plan.
- 2.51. **Transact** shall mean to send, submit, request, receive, assert, respond to, submit, route, subscribe to, or publish Message Content using NC HealthConnex. Transacting Message Content does not refer to the submission of Pharmacy Data or HIE Data to NC HealthConnex as required by Applicable Law.
- 2.52. **Treatment** shall have the meaning set forth at 45 C.F.R. §164.501 of the HIPAA Regulations; i.e. the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.
- 2.53. **User Access Policies** shall mean the policies and procedures adopted by each Party that addresses the access, use and disclosure of Pharmacy Data and HIE Data, Message Content, and the use and access of NC HealthConnex Resources.
- 2.54. **Workforce** shall have the meaning set forth at 45 C.F.R. §160.103 of the HIPAA Regulations.
- 3. **Incorporation of Recitals**. The Recitals set forth above are hereby incorporated into this Agreement in their entirety and shall be given full force and effect as if set forth in the body of this Agreement. This Agreement and together with all Exhibits shall be interpreted as an integrated agreement. Any ambiguity or material conflict between any of their provisions shall be resolved with an order of precedence among such documents as follows:
 - 3.01. Business Associate Agreement, Attachment 5
 - 3.02. This Agreement
 - 3.03. NC HIEA Policies and Procedures, Attachment 6
 - 3.04. Onboarding & Technical Specifications, Attachment 3
 - 3.05. eHealth Exchange Terms and Conditions, Attachment 9
 - 3.06. Fee Schedule, Attachment 8
 - 3.07. HIE Features, Attachment 7
 - 3.08. Addresses for Notice, Attachment 1
 - 3.09. Participating Entities, Attachment 4
 - 3.10. Participant Staff Contact Information, Attachment 2
 - 3.11. Technical Support, Attachment 10
- 4. **Purpose of this Agreement.** The purpose of this Agreement is to provide a legal framework that will enable Participants to connect to NC HealthConnex to submit Pharmacy Data and/or HIE Data to NC HIEA as required or permitted by § N.C.G.S. 90-414.4(b) and other Applicable Law, to Transact Message Content with other Participants, and to access and use the NC HealthConnex Resources. Such purposes are not intended to create or facilitate disclosure or sharing of Participant Confidential Information.
- 5. HIE Features; Fees.

- 5.01. **HIE Features.** Subject to the terms and conditions of this Agreement, Participant, Participating Entities, and Authorized Users (together and unless otherwise noted, "Participant") is authorized to use NC HealthConnex and the HIE Features identified in Attachment 7 as they are available. Participants shall be granted access to the HIE Features after execution of the Participation Agreement at the appropriate time during or at the completion of the Onboarding process. The HIE Features are subject to NC HIEA Policies and Procedures, which shall be available on the NC HIEA website.
 - a. NC HIEA reserves the right in its sole discretion to amend the HIE Features and shall have no liability to Participant or its Authorized Users for or arising out of such discontinuance of HIE Features. Participant is also entitled to receive support and maintenance as part of this Agreement and such Technical Support is described in Attachment 10 provided that Participant is not in default of this Agreement.
 - b. NC HIEA, along with any successors or assignees, shall not discontinue any offering that enables Participant to submit Pharmacy Data and/or HIE Data to NC HIEA for as long as it is required by Applicable Law, unless otherwise permitted by Section 19 (Term, Suspension & Termination) of this Agreement.

5.02. Fees.

- a. Pursuant to N.C.S.L. 2015-241, s. 12A.5, NC HIEA shall gradually become and remain one hundred percent (100%) receipt-supported. In consideration of the rights and obligations of the Parties hereunder, Participant shall pay to NC HIEA the fees set forth on the Fee Schedule attached hereto as Attachment 8 and incorporated herein by reference, at the times and in the manner, and subject to all other terms and conditions, as are set forth on such Fee Schedule, without notice or demand therefor, and without deduction or offset therefrom.
- b. Upon written Notice by NC HIEA to Participant at least one hundred eighty (180) days before the end of the initial term of this Agreement or the then current renewal term, NC HIEA reserves the right in its sole discretion to charge fees or to increase or decrease fees pursuant to this Agreement. NC HIEA shall have no liability to Participant for or arising out of such decision to charge, increase, or decrease in fees, provided any such change in fees shall only be effective for an extension or renewal of the then current term.

6. NC HIEA and the NC HIEA Advisory Board

- 6.01. **NC HIEA Authority**. NC HIEA has duties to provide oversight, facilitation and support for NC HealthConnex and Participants and Submitters by conducting activities including, but not limited to, the following:
 - a. Performing HIE Operations;
 - b. Establishing and modifying the clinical and demographic data elements and claims data elements for services paid for with Medicaid, State Health Plan, or other State funds within the defined Targeted Data Standards, provided that Participants shall be given reasonable advance notice of any modification of Targeted Data Standards, and such standards shall be consistent in all respects with the requirements of § N.C.G.S. 90-414.4, and otherwise permitted under all Applicable Laws.
 - c. Developing and amending the NC HIEA Policies and Procedures in accordance with Section 9 of this Agreement;
 - d. Receiving reports of HIPAA Breaches or Security Breaches and acting upon such reports in accordance with Section 14 of this Agreement (Breach Notification):
 - e. Suspending or terminating Participants in accordance with Section 19 of this Agreement (Suspension and Termination);

- f. Resolving Disputes with and between Participants in accordance with Section 20 of this Agreement (Dispute Resolution);
- g. Managing the amendment of this Agreement in accordance with Section 24.03 of this Agreement;
- h. Evaluating requests for the introduction of technical specifications into the production environment used by the Participants to submit HIE Data or to Transact Message Content;
- i. Coordinating to help ensure the interoperability with other health information exchange initiatives including, but not limited to, providing input into the broader ONC specifications activities and ONC standards and interoperability framework initiatives;
- j. Fulfilling all other responsibilities delegated by North Carolina General Assembly and the Participants to NC HIEA as set forth in this Agreement; and.
- k. To the extent permitted under Applicable Law, this grant of authority to NC HIEA is unconditional and does not require any further consideration or action by any Participant.
- 6.02. **NC HIEA Advisory Board**. The NC HIEA Advisory Board is organized and operates pursuant to N.C.G.S. §90-414.8. The NC HIEA Policies and Procedures will be amended in consultation with the Advisory Board as required by N.C.G.S. §90-414.7. Participants may attend any public meetings of the Advisory Board.

7. System Access.

7.01. **Policies**.

- a. The Parties shall have User Access Policies and Privacy and Security Policies as necessary or sufficient in the Parties' discretion to ensure proper use of NC HealthConnex and NC HealthConnex Resources pursuant to this Agreement.
- b. Each Party acknowledges that User Access Policies may differ among Participants, and that mutual benefits are available pursuant to this Agreement. Each Participant shall be responsible for determining whether and how to Transact Message Content based on the application of its business policies and Applicable Law to the information contained in the Message. Each Participant entering into this Agreement agrees to comply with the Applicable Law, this Agreement, and all applicable NC HIEA Policies and Procedures in submitting HIE Data and in Transacting Message Content.
- 7.02. **Authorized Users and HISPs**. The Parties shall require that all of their Participating Entities, Authorized Users, and HISPs Transact Message Content only in accordance with the terms and conditions of this Agreement, including without limitation those governing the use, confidentiality, privacy, and security of Message Content. The Parties shall discipline appropriately any of their Participating Entities or employee Authorized Users, or take appropriate contractual action with respect to contractor Authorized Users or HISPs, who fail to act in accordance with the terms and conditions of this Agreement relating to the privacy and security of Message Content, in accordance with the Parties' employee disciplinary policies and procedures and its contractor and vendor policies and contracts, respectively.
- 7.03. **Identification**. The Parties shall employ a process by which the Party, or its designee, validates sufficient information to uniquely identify each person seeking to become an Authorized User prior to issuing credentials that would grant the person access to the Party's System or NC HealthConnex Resources. See the NC HIEA User Access Policy and the Primary Provider User Guide for requirements related to assigning Authorized Users credentials for NC HealthConnex.
- 7.04. **Authentication**. Each Participant shall employ a process by which the Participant, or its designee, uses the credentials issued pursuant to this Section 7 to verify the identity of each Authorized User prior to enabling such Authorized User to Transact Message Content using NC HealthConnex. This

- process shall include the completion of an NC HIEA Onboarding process by the Participant before the Participant Account Administrator can assign user credentials for NC HealthConnex or for Direct Secure Messaging to users.
- 7.05. Participant Workforce Access. Each Participant Account Administrator shall only assign user credentials for NC HealthConnex or for Direct Secure Messaging through NC HealthConnex for Authorized Users who are Workforce members of Participant or its Participating Entities. In the event of changes in the employment status of an Authorized User, the Participant Account Administrator or other authorized personnel shall change the access or level thereof of the Authorized User within five (5) business days of the employment change.

8. Security.

- 8.01. General. The Parties shall be responsible for maintaining secure environments for their operations, data and Transactions. The Parties shall use appropriate safeguards to prevent use or disclosure of Pharmacy Data, HIE Data or Message Content other than as permitted by this Agreement, including appropriate administrative, physical, and technical safeguards that protect the confidentiality, integrity, and availability of HIE Data or Message Content. Appropriate safeguards for Participants shall be those identified in the HIPAA Security Rule, 45 C.F.R. Part 160 and Part 164, Subparts A and C, as safeguards, standards, "required" implementation specifications, and "addressable" implementation specifications to the extent that the "addressable" implementation specification are reasonable and appropriate in the Participant's environment. If an "addressable" implementation specification is not reasonable and appropriate in the Party's environment, then the Party must document why it would not be reasonable and appropriate to implement the implementation specification and implement an equivalent alternative measure if reasonable and appropriate.
- 8.02. **NC HealthConnex Security.** NC HIEA shall adhere to the Statewide Security Manual and Policies as required by N.C.G.S. §143B-1375 *et seq.*, Security of Information Technology, and all Applicable Law that governs data confidentiality, privacy, and security.
- 8.03. **Malicious Software**. The Parties shall ensure that they employ security controls that meet applicable industry, State or Federal standards so that Pharmacy Data, HIE Data, and Message Content being Transacted and any method of Transacting such information and Message Content will not introduce any viruses, worms, unauthorized cookies, trojans, malicious software, "malware," or other program, routine, subroutine, or data designed to disrupt the proper operation of a System or any part thereof or any hardware or software used by a Participant in connection therewith, or which, upon the occurrence of a certain event, the passage of time, or the taking of or failure to take any action, will cause a System or any part thereof or any hardware, software or data used by a Party in connection therewith, to be improperly accessed, destroyed, damaged, or otherwise made inoperable. In the absence of applicable industry standards, each Party shall use all commercially reasonable efforts to comply with the requirements of this Section.

9. NC HIEA Policies and Procedures.

- 9.01. **General Compliance.** The Parties shall comply with the NC HIEA Policies and Procedures adopted by NC HIEA in accordance with this Agreement. The NC HIEA Policies and Procedures will be made available on the NC HIEA website and by request. See https://hiea.nc.gov/providers/nc-hiea-policies.
- 9.02. **Development of the NC HIEA Policies and Procedures.** The NC HIEA may amend, repeal, replace, or adopt new Policies and Procedures at any time. Any changes to the NC HIEA Policies and Procedures will be developed and amended in consultation with the Advisory Board as required by N.C.G.S. § 90-414.7
- 9.03. NC HIEA Policies and Procedures Change Process.

- a. Prior to approving any new, amended, repealed or replaced NC HIEA Policies and Procedures, the NC HIEA may provide notice of proposed changes to Participants. The NC HIEA may solicit and consider comments from the Participants on the new, amended, repealed or replaced NC HIEA Policies and Procedures.
- b. Adoption of changes shall be determined by the NC HIEA in consultation with the Advisory Board.
- c. NC HIEA shall notify all Participants of amended, repealed or replaced NC HIEA Policies and Procedures at least thirty (30) calendar days prior to the effective date of such amended, repealed or replaced NC HIEA Policies and Procedures, or such longer period as the NC HIEA shall determine after consultation with the NC HIEA Advisory Board.

10. Obligations of NC HIEA.

- 10.01. NC HIEA shall maintain the functionality of NC HealthConnex and associated NC HealthConnex Resources provided by NC HIEA, and provide or arrange for the provision of such service, security, and other updates to NC HealthConnex as NC HIEA determines to be appropriate from time to time.
- 10.02. Pharmacy Data, HIE Data, Message Content, data associated with Transactions, PHI or ePHI, or other Confidential Information of Participant shall be accessed, used, or disclosed by NC HIEA and NC HIEA Workforce members, or the Workforce members of any subcontractors or technology partners of NC HIEA, to the extent necessary to conduct HIE Operations and for Permitted Purposes. Pursuant to N.C.G.S. 90-414.6, NC HIEA shall not allow Pharmacy Data and HIE Data it receives pursuant to N.C.G.S. 90-414.4 or any other provision of Article 29B of the North Carolina General Statutes to be used or disclosed by or to any person or entity for commercial purposes.

10.03. **Opt Out.**

- a. NC HIEA will provide information and education to Participants about the right of Individuals on a continuing basis to Opt Out or to rescind a decision to Opt Out.
- b. After an Individual has notified NC HIEA of his or her decision to Opt Out of NC HealthConnex, NC HIEA will ensure that the Individual's HIE Data will not be disclosed to any other entities unless as required or permitted by law, or as permitted by N.C.G.S § 90-414.10.
- 10.04. **Obligations under 42 C.F.R. Part 2 as a Qualified Service Organization:** NC HIEA may act as a Qualified Service Organization on behalf of Participant in the event Participant or a unit within Participant's organization is a substance abuse treatment program that must comply with 42 C.F.R. Part 2. To the extent the PHI received by NC HIEA is protected by the 42 C.F.R. Part 2 (hereafter "Part 2 Data"), NC HIEA acknowledges that in receiving, storing, processing or otherwise dealing with Part 2 Data, NC HIEA is fully bound by the Part 2 Regulations. If necessary, NC HIEA will resist in judicial proceedings any efforts to obtain access to Part 2 Data except as permitted by 42 C.F.R. Part 2. Participant shall not send Part 2 Data to NC HealthConnex unless and until NC HIEA notifies Participant in writing that NC HIEA can accept Part 2 Data.
- 10.05. **Disclosure To Covered Entities, Business Associates, and Approved Third Parties.** NC HIEA shall display on its public website the Covered Entities, Business Associates, and Approved Third Parties that have been granted access to NC HealthConnex or to HIE Data pursuant to N.C.G.S.§ 90-414.7(b)(6) through (9) and other Applicable Law.

11. Obligations of Participants.

11.01. **Submission of Pharmacy Data to NC HIEA.** Pursuant to the Statewide Health Information Exchange Act, , Participant shall submit all data elements set forth in the Targeted Data Standards in Attachment 3 to the extent possible for, at a minimum, claims data concerning all health care services

- rendered by Participant to Medicaid, State Health Plan, and other State-funded health care program beneficiaries.
- 11.02. **Prohibition of the Exchange of Certain Data.** Participant shall not submit data to NC HIEA or Transact Message Content through NC HealthConnex in contravention of Applicable Law without an Authorization if one is required by Applicable Law before such disclosure is made.
- 11.03. **Equipment and Software**. Each Participant shall be responsible for procuring, and assuring that its Participating Entities and Authorized Users have or have access to, all equipment and software necessary for it to submit Pharmacy Data to NC HIEA and to Transact Message Content. Each Participant shall ensure that all computers and electronic devices owned or leased by the Participant and its Authorized Users to be used are properly configured, including, but not limited to, the base workstation operating system, web browser, and Internet connectivity.
- 11.04. **Participant Onboarding and Technical Specifications.** Each Participant shall comply with the Onboarding and Technical Specifications developed by NC HIEA during the Onboarding process to initiate a connection to NC HealthConnex and while submitting Pharmacy Data to NC HIEA.

11.05. Minimum Standards for Transacting Message Content for Treatment.

- a. All Participants that request, or allow their respective Participating Entities and Authorized Users to request, Message Content for Treatment shall have a corresponding reciprocal duty to respond to Messages that request Message Content for Treatment. A Participant shall fulfill its duty to respond by either (i) responding to the Message with the requested Message Content or, (ii) responding with a standardized response that indicates the Message Content is not available or cannot be exchanged. All responses to Messages shall comply with NC HIEA Policies and Procedures, this Agreement, any agreements between Participant, Participating Entities, and their Authorized Users, and Applicable Law. Participants may, but are not required to, Transact Message Content for a Permitted Purpose other than Treatment. Nothing in this Section 11 shall require a disclosure that is contrary to a restriction placed on the Message Content by a patient pursuant to Applicable Law.
- b. Each Participant that requests, or allows its respective Participating Entities or Authorized Users to request, Message Content for Treatment shall Transact Message Content with all other Participants for Treatment, in accordance with Sections 7, 11.05(a), and 13 of this Agreement. If a Participant desires to stop Transacting Message Content with another Participant based on the other Participant's acts or omissions in connection with this Agreement, the Participant may temporarily stop Transacting Message Content with such Participant either through modification of its User Access Policies or through some other mechanism, to the extent necessary to address the Participant's concerns. If any such cessation occurs, the Participant shall provide a Notification to NC HIEA of such cessation and the reasons supporting the cessation. The Participants shall submit the Dispute leading to the cessation to the Dispute Resolution Process in Section 20. If the cessation is a result of a HIPAA Breach or Security Breach that was reported to, and deemed resolved by, NC HIEA pursuant to Section 14, the Participants involved in the HIPAA Breach or Security Breach and the cessation shall engage in the Dispute Resolution Process in Section 20 in an effort to attempt to reestablish trust and resolve any security concems arising from the HIPAA Breach or Security Breach.

11.06. Use of Message Content and NC HealthConnex Resources.

- a. **Permitted Purpose**. Participants shall only Transact Message Content and use the NC HealthConnex Resources for a Permitted Purpose as defined in this Agreement. Each Participant shall require that its Participating Entities and Authorized Users comply with this Section 11.
- b. **Permitted Future Uses.** Subject to this Section 11 and Section 19.05, Recipients may retain, use and re-disclose Message Content,HIE Data, or Pharmacy Data accessed from NC HealthConnex Resources in accordance with Applicable Law and the Recipient's record

- retention policies and procedures. If the Recipient is a Participant that is a Business Associate of its Authorized Users, such Participant may retain, use and re-disclose Message Content in accordance with Applicable Law and the agreements between the Participant and its Authorized Users.
- c. Management Uses. NC HIEA may request information from Participants, and Participants shall provide requested information, for the purposes listed in Section 6.01 of this Agreement. Any information, other than Message Content, provided by a Participant to NC HIEA shall be labeled as Confidential Participant Information and shall be treated as such in accordance with Section 16.
- 11.07. **Specific Duties of a Participant When Submitting a Message**. Whenever a Participant acts as a Submitter by submitting a Message to another Participant, the Submitter shall be responsible for:
 - a. Submitting each Message in compliance with Applicable Law, this Agreement, the applicable NC HIEA Policies and Procedures including, but not limited to, representing that the Message is:
 - 1. for a Permitted Purpose;
 - 2. submitted by a Submitter who has the requisite authority to make such a submission;
 - 3. supported by appropriate legal authority for Transacting the Message Content including, but not limited to, any consent or Authorization, if required by Applicable Law; and
 - 4. submitted to the intended Recipient.
 - b. Representing that assertions or statements related to the submitted Message are true and accurate, if such assertions or statements are required by the NC HIEA Policies and Procedures.
 - c. Submitting a copy of the Authorization, if the Submitter is requesting Message Content from another Participant, based on the Permitted Purposes described in Section 2.39. Nothing in this Section shall be interpreted as requiring a Submitter who is requesting Message Content to obtain or transmit an Authorization for a request based on a Permitted Purposes other than the one described in Section 2.39 even though certain other Participants require such Authorization to comply with Applicable Law.
- 11.08. **Participant Duty to Terminate Participation**. If, as a result of a change made by NC HIEA in accordance with this Section 11, a Participant will not be able to comply with the NC HIEA Policies and Procedures or the Onboarding or Technical Specifications, or does not otherwise desire to continue to Transact Message Content with other Participants or to use NC HealthConnex Resources after such change becomes effective, then such Participant shall terminate this Agreement in accordance with Section 19.02.
- 11.09. Compliance with the eHealth Exchange DURSA. When Transacting Message Content over the nationwide eHealth Exchange through NC HealthConnex, Participant shall (i) comply with all Applicable Law; (ii) reasonably cooperate with NC HIEA on issues related to this Agreement and with the eHealth Exchange DURSA; (iii) Transact Message Content only for a permitted purposes as outlined in Attachment 9; (iv) use Message Content received from another Participant in accordance with the terms and conditions of this Agreement; (v) as soon as reasonably practicable after determining that a HIPAA Breach occurred, report such Breach to NC HIEA and any affected Participants; (vi) refrain from disclosing to any other person any passwords or other security measures issued to the Authorized User by NC HIEA or the Participant Account Administrator; and (vii) comply with the provisions outlined in Attachment 9.
- 11.10. **Participating Entities**. Participating Entities that will be participating in NC HealthConnex under the authority of Participant shall be listed in Attachment 4 of this Agreement and each party so listed shall be individually entitled to the rights and subject to the obligations set forth in the Participation

Agreement. Participating Entities may act under the authority of one Participant of NC HealthConnex or as multiple Participants with a separate Participation Agreement for each Participating Entity.

- 11.11. **Patient Education of the Right to Opt Out.** Participant shall establish a process for notifying Individuals about:
 - a. the benefits of NC HealthConnex;
 - b. the Individual's right to Opt Out and the potential consequences to Individuals of Opting Out; and
 - c. the Individual's right to rescind a previous decision to Opt Out.
- 11.12. **Creation of Test Data**. Participant shall submit test data that closely approximates the production Pharmacy Data intended to be submitted to NC HIEA. Any Test data that has been created, or will be created in the future, shall not contain any personal or individually identifiable information, including without limitation, PHI.

12. License to NC HealthConnex Resources.

- 12.01. Participant is hereby granted a nonexclusive, nontransferable, revocable and limited license to the NC HealthConnex Resources solely for use as a Participant in performance of this Agreement. Participant shall not (a) sell, sublicense, transfer, exploit or, other than pursuant to this Agreement, or (b) reverse engineer, decompile, disassemble, or otherwise attempt to discover the source code to any NC HealthConnex Resources. THE NC HEALTHCONNEX RESOURCES ARE PROVIDED "AS IS" AND "AS AVAILABLE" WITHOUT ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT.
- 12.02. Exchange of Data for Meaningful Use. If Participant elects to utilize NC HealthConnex for Meaningful Use purposes, Participant is granted a nonexclusive, nontransferable, revocable and limited license to the NC HealthConnex Resources for the purpose of exchanging clinical and demographic information through NC HealthConnex to comply with Meaningful Use or other federal guidelines. Participant also grants NC HIEA a nonexclusive, nontransferable, revocable and limited license to access, use, and store data submitted to or through NC HealthConnex under this subsection.

13. Privacy and Security.

- 13.01. **Applicability of HIPAA Regulations**. Pharmacy Data and HIE Data Message Content contains PHI. Furthermore, some, but not all, Participants are either a Covered Entity or a Business Associate of a Covered Entity. Because the Participants are limited to Transacting Message Content for only a Permitted Purpose, the Participants do not intend to become each other's Business Associate by virtue of signing this Agreement or Transacting Message Content. As a result, this Agreement is not intended to serve as a Business Associate Agreement among the Participants. To support the privacy, confidentiality, and security of the Message Content, each Participant agrees as follows:
 - a. If the Participant is a Covered Entity, the Participant does, and at all times shall, comply with the HIPAA Regulations to the extent applicable.
 - b. If the Participant is a Business Associate of a Covered Entity, the Participant does, and shall at all times, comply with the provisions of its Business Associate Agreements (or for governmental entities relying upon 45 C.F.R. §164.504(e)(3)(i)(A), its Memoranda of Understanding) and Applicable Law.

- c. If Participant is a governmental entity, the Participant shall comply with the applicable privacy and security laws.
- 14. **Breach Notification.** The following provisions apply to both a HIPAA Breach and a Security Breach as defined in Section 2 (Definitions). For this Section 14 only, the term "Breach" refers to either a HIPAA Breach or a Security Breach.
 - 14.01. The Parties agree that as soon as reasonably practicable, but no later than twenty-four (24) hours after determining that a Breach has occurred, the Parties shall provide a Notification to the other Party and to all Participants likely impacted by the Breach. Participant must also alert the SAS Help Desk at HIEsupport@sas.com and describe the incident as soon as reasonably practicable, but no later than twenty-four (24) hours after determining that a Breach has occurred. The Notification should include sufficient information for the other Party or other Participants to understand the nature of the Breach. For instance, such Notification could include, to the extent available at the time of the Notification, the following information:
 - a. One or two sentence description of the Breach
 - b. Description of the roles of the people involved in the Breach (e.g. employees, Authorized Users, service providers, unauthorized persons, etc.)
 - c. The type of Message Content Breached
 - d. Participants likely impacted by the Breach
 - e. Number of individuals or records impacted/estimated to be impacted by the Breach
 - f. Actions taken by the Participant to mitigate the Breach
 - g. Current Status of the HIPAA Breach (under investigation or resolved)
 - h. Corrective action taken and steps planned to be taken to prevent a similar Breach.
 - 14.02. The Parties shall supplement the information contained in the Notification as it becomes available and cooperate with other Participants in accordance with Section 1(e) of this Agreement. The Notification required by this Section 14 shall not include any PHI. If, on the basis of the Notification, a Participant desires to stop Transacting Message Content with the Participant that reported a Breach, it shall stop Transacting Message Content in accordance with Section 1 of this Agreement. If, on the basis of the Notification, NC HIEA determines that (i) the other Participants that have not been notified of the Breach would benefit from a summary of the Notification or (ii) a summary of the Notification to the other Participants would enhance the security of NC HealthConnex, it may provide, in a timely manner, a summary to such Participants that does not identify any of the Participants or individuals involved in the Breach.
 - 14.03. Information provided by a Participant in accordance with this Section, except Message Content, may be "Confidential Participant Information." Such "Confidential Participant Information" shall be treated in accordance with Section 16.
 - 14.04. This Section shall not be deemed to supersede a Participant's obligations (if any) under relevant security incident, Breach notification or confidentiality provisions of Applicable Law.
 - 14.05. Compliance with this Section shall not relieve Participants of any other security incident or Breach reporting requirements under Applicable Law including, but not limited to, those related to consumers.

15. Representations and Warranties.

15.01. **Accurate Participant Information**. Except to the extent prohibited by Applicable Law, each Participant has provided, and shall continue to provide, NC HIEA with all information reasonably requested by NC HIEA and needed by NC HIEA to discharge its duties under this Agreement or

- Applicable Law, including during the Dispute Resolution Process. Any information provided by a Participant to NC HIEA shall be responsive and accurate. Each Participant shall provide Notice to NC HIEA if any information provided by the Participant to NC HIEA materially changes. Each Participant acknowledges that NC HIEA reserves the right to confirm or otherwise verify or check, in its sole discretion, the completeness and accuracy of any information provided by a Participant at any time and each Participant shall reasonably cooperate with NC HIEA in such actions, given reasonable prior notice. This Section 15.01 does not apply to Pharmacy Data or HIE Data.
- 15.02. **Execution of the Participation Agreement**. Prior to submitting Pharmacy Data to NC HIEA, Transacting Message Content with other Participants, or accessing and using NC HealthConnex Resources, each Participant shall have executed this Agreement and returned an executed copy of this Agreement to NC HIEA. In doing so, the Participant affirms that it has full power and authority to enter into and perform this Agreement and has taken whatever measures necessary to obtain all required approvals or consents in order for it to execute this Agreement. The representatives signing this Agreement on behalf of the Participants affirm that they have been properly authorized and empowered to enter into this Agreement on behalf of the Participant and any Participating Entities.
- 15.03. Compliance with this Agreement. Except to the extent prohibited by Applicable Law, each Party shall comply fully with all provisions of this Agreement. To the extent that a Participant delegates its duties under this Agreement to a third party (by contract or otherwise) and such third party will have access to Message Content and NC HealthConnex Resources, that delegation shall be in writing and require the third party, prior to Transacting Message Content with any Participants or accessing and using NC HealthConnex Resources, to agree to the same restrictions and conditions that apply through this Agreement to a Participant. Participant represents and warrants that disclosures to other Participants or third parties as necessary to perform this Agreement are permissible under the Privacy Rule and any other Applicable Law.
- 15.04. **Agreements with Technology Partners**. To the extent that the Parties use technology partners or subcontractors in connection with the Participant's submission of Pharmacy Data or Transaction of Message Content, each Party affirms that it has valid and enforceable agreements with each of its technology partners, including HISPs, that require the technology partner to, at a minimum: (i) comply with Applicable Law; (ii) protect the privacy and security of any Pharmacy Data, HIE Data, or Message Content to which it has access; (iii) as soon as reasonably practicable after determining that a HIPAA Breach or Security occurred, report such Breach to the Party; and (iv) reasonably cooperate with the other Party and other Participants on issues related to this Agreement, under the direction of the Party.
- 15.05. Accuracy of Pharmacy Data and Message Content. When acting as a Submitter, each Participant, in accordance with Section 17.02, hereby represents that at the time of transmission, the Pharmacy Data and Message Content it provides is (a) an accurate representation of the data contained in, or available through, its System, (b) sent from a System that employs security controls that meet industry standards so that the information and Message Content being transmitted are intended to be free from malicious software, and (c) provided in a timely manner and in accordance with the NC HIEA Policies and Procedures. Other than those representations in Sections 15.05, 15.06, and 15.07, the Submitter makes no other representation, express or implied, about the Pharmacy Data or Message Content.
- 15.06. Express Warranty of Authority to Submit Pharmacy Data and to Transact Message Content. To the extent each Participant is a Submitter and is submitting Pharmacy Data to NC HIEA or providing Message Content to a Recipient, each Participant represents and warrants that it has sufficient authority to submit such Pharmacy Data or to Transact such Message Content.

- 15.07. **Use of Message Content and NC HealthConnex Resources.** Each Participant hereby represents and warrants that it shall use the Message Content and NC HealthConnex Resources only in accordance with the provisions of this Agreement.
- 15.08. **Auditing**. Each Party represents that, through its agents, employees, and independent contractors, it shall have the ability to monitor and audit all access to and use of its System related to this Agreement, for system administration, security, and other legitimate purposes. Each Party shall perform those auditing activities required by the NC HIEA Policies and Procedures.
- 15.09. **Compliance with Laws**. Each Party shall, at all times, fully comply with all Applicable Law relating to this Agreement, the Transaction of Message Content for a Permitted Purpose, and the use of Message Content.
- 15.10. **Absence of Final Orders.** Each Participant hereby represents and warrants that, as of the Effective Date, it is not subject to a final order issued by any federal, State, local or international court of competent jurisdiction or regulatory or law enforcement organization, which will materially impact the Participant's ability to fulfill its obligations under this Agreement. Each Participant shall inform NC HIEA if at any point during the term of this Agreement it becomes subject to such an order.

16. Confidential Information.

- 16.01. **Confidential Participant Information.** Each Receiving Party shall hold all Confidential Participant Information in confidence and agrees that it shall not, during the term or after the termination of this Agreement, redisclose to any person or entity, nor use for its own business or benefit, any information obtained by it in connection with this Agreement, unless such use or redisclosure is permitted by the terms of this Agreement.
- 16.02. Application of the North Carolina Public Records Act. NC HIEA may receive from Participant certain confidential types of information described in N.C.G.S. §132-1 et seq. and Section 2.06, which NC HIEA shall protect in accordance with Section 16.01. Participant may designate data and information as confidential, consistent with and to the extent permitted under Applicable Law, by marking the top and bottom of pages containing confidential information with a legend in boldface "CONFIDENTIAL" or by identifying electronically supplied information as "CONFIDENTIAL." NC HIEA shall promptly notify Participant of a public record request involving information that Participant has deemed confidential pursuant to this Agreement. Participant must then notify NC HIEA in writing whether to disclose the information or to restrict disclosure. The Parties shall cooperate and assist each other in preparing an appropriate response to the request or action, if the records responsive to the request include Confidential Submitter Information. If an action is brought pursuant to N.C.G.S. §132-9 to compel NC HIEA to disclose information marked confidential, NC HIEA shall provide Participant prompt written notice of such action. If the Participant has requested in writing that NC HIEA not disclose the Confidential Participant Information, Participant shall promptly intervene in the action through its counsel and participate in defending NC HIEA, including any public official(s) or public employee(s). The Participant agrees that it shall hold NC HIEA and any official(s) and individual(s) harmless from any and all damages, costs, and attorneys' fees awarded against NC HIEA in the action. NC HIEA shall have the right, at its option and expense, to participate in the defense of the action through its counsel. NC HIEA shall have no liability to Participant with respect to the disclosure of Confidential Participant Information ordered by a court of competent jurisdiction pursuant to N.C.G.S. §132-9 or other applicable law.

17. Disclaimers.

- 17.01. **Reliance on a System**. Each Participant acknowledges and agrees that: (i) the Pharmacy Data, HIE Data, and Message Content received or provided by, or through, its System is drawn from numerous sources, and (ii) it can only confirm that, at the time Message Content is Transacted, the information and Message Content Transacted are an accurate representation of data contained in, or available through, its System. Nothing in this Agreement shall be deemed to impose responsibility or liability on a Participant related to the clinical accuracy, content or completeness of any Pharmacy Data, HIE Data, or Message Content provided pursuant to this Agreement. The Participants acknowledge that other Participants' Digital Credentials may be activated, suspended or revoked at any time or the Participant may suspend its participation; therefore, Participants may not rely upon the availability of Pharmacy Data, HIE Data, or a particular Participant's Message Content.
- 17.02. **Incomplete Medical Record**. Each Participant acknowledges that Pharmacy Data, HIE Data, or Message Content Transacted by Participants may not include the individual's full and complete medical record or history. Such Pharmacy Data, HIE Data, or Message Content will only include that data which is the subject of the Message and available for exchange among Participants.
- 17.03. Patient Care. Pharmacy Data, HIE Data or Message Content obtained through NC HealthConnex is not a substitute for any Participant, if that person/entity is a Health Care Provider, obtaining whatever information he/she/it deems necessary, in his/her professional judgment, for the proper treatment of a patient. The Participant, if he/she/it is a Health Care Provider, shall be solely responsible for all decisions and actions taken or not taken involving patient care, utilization management, and quality management for his/her/its respective patients and clients resulting from, or in any way related to, the use of the NC HealthConnex, HIE Features, and NC HIEA Policies and Procedures agreed to by the Participants pursuant to this Agreement or the Pharmacy Data, HIE Data, or Message Content made available thereby. By executing this Agreement or Transacting Message Content, neither Participant, Participating Entity, or an Authorized User assumes any responsibility or liability for the health care services provided by any other Participant, Participating Entity, or Authorized User to a patient.
- 17.04. Carrier lines. All Participants acknowledge that the submission of Pharmacy Data to NC HIEA or the Transaction of Message Content between Participants is to be provided over various facilities and communications lines, and information shall be transmitted over local exchange and Internet backbone carrier lines and through routers, switches, and other devices (collectively, "carrier lines") owned, maintained, and serviced by third-party carriers, utilities, and Internet service providers, all of which may be beyond the Participants' control. Provided a Participant uses reasonable security measures, no less stringent than those directives, instructions, and specifications contained in this Agreement and the NC HIEA Policies and Procedures, the Participants assume no liability for or relating to the integrity, privacy, security, confidentiality, or use of any information while it is transmitted over those carrier lines, which are beyond the Participants' control, or any delay, failure, interruption, interception, loss, transmission, or corruption of any Pharmacy Data, HIE Data, Message Content, or other information attributable to transmission over those carrier lines which are beyond the Participants' control. Use of the carrier lines is solely at the Participants' risk and is subject to all Applicable Law.
- 17.05. No Warranties. EXCEPT AS REPRESENTED IN SECTIONS 15.05 AND 15.06, PHARMACY DATA, HIE DATA, AND MESSAGE CONTENT ARE PROVIDED "AS IS" AND "AS AVAILABLE" WITHOUT ANY WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE **IMPLIED** WARRANTIES OF MERCHANTABILITY, **FITNESS PARTICULAR AND** FOR Α PURPOSE, NONINFRINGEMENT. IT IS EXPRESSLY AGREED THAT IN NO EVENT SHALL THE PARTIES BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, OR

EXEMPLARY DAMAGES, INCLUDING BUT NOT LIMITED TO, LOSS OF PROFITS OR REVENUES, LOSS OF USE, OR LOSS OF INFORMATION OR DATA, WHETHER A CLAIM FOR ANY SUCH LIABILITY OR DAMAGES IS PREMISED UPON BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR ANY OTHER THEORIES OF LIABILITY, EVEN IF THE PARTIES HAVE BEEN APPRISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OCCURRING. THE PARTIES DISCLAIM ANY AND ALL LIABILITY FOR ERRONEOUS TRANSMISSIONS AND LOSS OF SERVICE RESULTING FROM COMMUNICATION FAILURES BY TELECOMMUNICATION SERVICE PROVIDERS OR OTHER THIRD PARTIES.

18. Liability.

- 18.01. Participant Liability. Participant shall be responsible for its acts and omissions and not for the acts or omissions of NC HIEA or any other Participant. In circumstances involving harm to other Participants caused by the acts or omissions of individuals who Transact Message Content or Confidential Participant Information through the Participant or by use of any password, identifier, or log-on received or obtained directly or indirectly, lawfully or unlawfully, from the Participant or any of the Participating Entities or Authorized Users, each Participant shall be responsible for such harm to the extent that the individual's access was caused by the Participant's breach of the Agreement or its negligent conduct for which there is a civil remedy under Applicable Law. Notwithstanding any provision in this Agreement to the contrary, Participant shall not be liable for any act or omission if a cause of action for such act or omission is otherwise prohibited by Applicable Law. This Section shall not be construed as a hold harmless or indemnification provision.
- 18.02. NC HIEA Liability. Participant shall not hold NC HIEA, the NC HIEA Advisory Board, or any of their members liable for or relating to any impairment of the privacy, security, confidentiality, integrity, availability, or restricted use of any information on a System resulting from any Participant's actions or failures to act, except to the extent such action or failure to act was directed by NC HIEA. NC HIEA is not liable for any damages resulting from loss of Pharmacy Data, HIE Data, or Message Content, or use of Message Content by Approved Third Parties following transfer or Transaction of such by NC HIEA. NC HIEA disclaims all liability connected to disclosures made to NC HIEA by Participant in contravention of Applicable Law. NC HIEA does not waive any defenses or rights based upon sovereign immunity of the State of North Carolina.
- 18.03. **Effect of Agreement**. Except as provided in Section 17 (Disclaimers) and Section 20 (Dispute Resolution), nothing in this Agreement shall be construed to restrict a Participant's right to pursue all remedies available under law for damages or other relief arising from acts or omissions of other Participants related to this Agreement, or to limit any rights, immunities or defenses to which a Participant or Authorized User may be entitled under Applicable Law.

19. Term, Suspension and Termination.

19.01. **Term.** The initial term of this Agreement shall begin on the Effective Date and extend for one year measured from the Effective Date. The Parties shall complete all necessary Onboarding activities and meet any Onboarding and Technical Specifications during the period following execution of this Agreement and prior to the Go Live Date. Upon the expiration of the initial term, this Agreement shall automatically renew for successive one-year terms unless terminated pursuant to this Section 19.

19.02. Suspension or Termination by Participant.

a. A Participant may voluntarily suspend its own right to Transact Message Content or to use NC HealthConnex Resources by Notifying NC HIEA of its voluntary suspension. Once a Participant

- has properly Notified NC HIEA of its voluntary suspension, neither the Participant, nor its Participating Entities or Authorized Users, shall Transact Message Content until the voluntary suspension has ended and the Participant has Notified NC HIEA that the suspension has ended. During the period of the voluntary suspension, the Participant's inability to Transact Message Content and comply with those terms this Agreement that require Transaction of Message Content shall not be deemed a breach of this Agreement.
- b. A Participant may terminate its own right to Transact Message Content or to use NC HealthConnex Resources by terminating this Agreement, with or without cause, by giving NC HIEA at least five (5) business days prior written Notice. Once proper Notice is given, NC HIEA shall be empowered to revoke the Participant's Digital Credentials as of the date of termination specified in the Notice. Once NC HIEA revokes the Participant's Digital Credentials, NC HIEA shall provide a notice of the revocation to the remaining Participants.
- 19.03. Suspension by NC HIEA. Upon NC HIEA completing a preliminary investigation and determining that there is a substantial likelihood that a Participant's acts or omissions create an immediate threat or will cause irreparable harm to another party including, but not limited to, a Participant; a Participating Entity; an Authorized User; the integrity or operation of NC HealthConnex; or an individual whose Message Content is Transacted using the Onboarding and Technical Specifications; the Participants hereby grant to NC HIEA the power to summarily suspend, to the extent necessary to address the threat posed by the Participant, a Participant's Digital Credentials, pending the submission and approval of a corrective action plan, as provided in this Section. Upon suspension, NC HIEA shall immediately suspend the Participant's Digital Credentials and within twelve (12) business hours of suspending a Participant's right to Transact Message Content (i) provide a notice of such suspension to all Participants; and (ii) provide to the suspended Participant a written summary of the reasons for the suspension. The Participant shall use reasonable efforts to respond to the suspension Notice with a detailed plan of correction or an objection to the suspension within three (3) business days or, if such submission is not reasonably feasible within three (3) business days, then at the earliest practicable time. If the Participant submits a plan of correction, NC HIEA shall, within five (5) business days, review and either accept or reject the plan of correction. If the plan of correction is accepted, NC HIEA shall, upon completion of the plan of correction, reinstate the Participant's Digital Credentials and provide a notice to all Participants of such reinstatement. If the plan of correction is rejected, the Participant's suspension will continue, during which time NC HIEA and the Participant shall work in good faith to develop a plan of correction that is acceptable to both the Participant and NC HIEA. At any time after NC HIEA rejects a Participant's plan of correction, either the Participant or NC HIEA may submit a Dispute to the Dispute Resolution Process described in Section 20. If NC HIEA and the Participant cannot reach agreement on a plan of correction through the Dispute Resolution Process, NC HIEA may terminate the Participant in accordance with Section 19.04.
- 19.04. **Termination by NC HIEA**. The Parties hereby acknowledge and agree that NC HIEA may terminate a Participant's connection to NC HealthConnex and Participant's right to Transact Message Content as follows:
 - a. After taking a suspension action in accordance with Section 19.03 when there is a substantial likelihood that the Participant's acts or omissions create an immediate threat or will cause irreparable harm to another party including, but not limited to, a Participant, a Participating Entity, or an Authorized User, integrity or operation of NC HealthConnex, or an individual whose Message Content is Transacted; or
 - b. In the event a Participant is in material default of the performance of a duty or obligation imposed upon it by this Agreement and such default has not been substantially cured within thirty (30)

- calendar days following receipt by the defaulting Participant of written Notice thereof from NC HIEA.
- c. A Participant whose Digital Credentials are revoked by virtue of termination may appeal such revocation through the Dispute Resolution Process. However, during the pendency of any such appeal, the Participant's Digital Credentials may continue to be revoked at the discretion of NC HIEA.
- 19.05. **Effect of Termination.** Upon any termination of this Agreement for any reason, the terminated party shall cease to be a Participant and thereupon and thereafter neither that Party nor its Authorized Users shall have any rights to submit Pharmacy Data or have access to the NC HealthConnex Resources or Transact Message Content with other Participants (unless such Authorized Users have an independent right to Transact Message Content through another Participant). NC HIEA shall revoke a terminated Participant's Digital Credentials, which will terminate Participant's ability to Transact Message Content. Once NC HIEA revokes the Participant's Digital Credentials, NC HIEA shall provide a notice of such revocation to the remaining Participants. In the event that any Participant(s) is terminated, this Agreement will remain in full force and effect with respect to all other Participants.
- 19.06. **Disposition of Message Content on Termination**. At the time of termination, Recipient may, at its election, retain Message Content on Recipient's System in accordance with the Recipient's document and data retention policies and procedures, Applicable Law, and the terms and conditions of this Agreement.
- 19.07. **Availability of Funds.** The HIE Features are expressly contingent upon and subject to the appropriation, allocation, and availability of funds to NC HIEA for the purposes set forth in this Agreement. Notwithstanding NC HIEA's authority to become self-supporting, HIE Features and operations funded in whole or in part by federal funds or appropriations by the N.C. General Assembly shall be subject to and contingent upon the continuing availability of such funds for the purposes of this Agreement. If funds to support NC HIEA operations or HIE Features are not available, NC HIEA will provide written notification to Participant together with notice of termination. NC HIEA shall have no liability or continuing obligation if this Agreement is terminated for lack of available funds.

20. Dispute Resolution.

- 20.01. General. The Parties acknowledge that it may be in their best interest to resolve Disputes through an alternative Dispute Resolution Process rather than through civil litigation. The Parties have reached this conclusion based upon the fact that the legal and factual issues involved in this Agreement are unique, novel, and complex and limited case law exists which addresses the legal issues that could arise from this Agreement. Except in accordance with Section 20.02, if a Party refuses to participate in the Dispute Resolution Process, such refusal shall constitute a material breach of this Agreement and may be grounds for termination in accordance with Section 19.04. During the time the Parties are attempting to resolve any dispute, each shall proceed diligently to perform their respective duties and responsibilities under this Agreement. If a dispute cannot be resolved between the Parties within thirty (30) days after delivery of notice, either Party may elect to exercise any other remedies available under this Agreement, or at law; or invite the other party to submit the matter to mediation.
- 20.02. **Immediate Injunctive Relief**. Notwithstanding Section 20.01, a Party may be relieved of its obligation to participate in the Dispute Resolution Process if such Party (i) believes that another Party's acts or omissions create an immediate threat to the confidentiality, privacy or security of Message Content or will cause irreparable harm to another party (Participant, Authorized User, the integrity or operation of NC HealthConnex, or consumer) and (ii) pursues immediate injunctive relief

- against such other Participant in a court of competent jurisdiction. The Party pursuing immediate injunctive relief must provide a Notification to the other Party of such action within 24 hours of filing for the injunctive relief and of the result of the action within 24 hours of learning of same.
- 20.03. If the injunctive relief sought in Section 20.02 is not granted and the Party seeking such relief chooses to pursue the Dispute, the Parties must then submit to the Dispute Resolution Process in accordance with this Section 20.03. If both Parties agree to submit the matter to mediation, the following actions shall be taken:
 - a. Each Party shall recommend a mediator certified by the North Carolina Courts after first determining that the recommended mediator, and said mediator's firm, if any, have no conflict or prior knowledge of the Dispute to be resolved, and no prior work for or against either Party; and.
 - b. The recommended mediators must have knowledge of the general subject matter of the Applicable Law; and,
 - c. The recommended mediators must be able to execute and deliver a satisfactory confidentiality and non-disclosure agreement if information exempt from disclosure under N.C. Gen. Stat. §132-1, et seq. is relevant or material to the matter to be resolved; and,
 - d. Recommended mediators and their respective contact and qualification information shall be exchanged within five (5) days to each Party following the agreement to mediate; and
 - e. Unless the Parties mutually agree to select a particular mediator, the selection of a mediator shall be determined by the mediator's earliest available date to initiate mediation. Any agreement to mediate shall require the Parties to appear and mediate the matter in good faith in accordance with the schedule and calendar established by the Mediator; and,
 - f. Provided, however, that this term shall not constitute an agreement by either Party to mediate or arbitrate any dispute; and that any agreement to mediate may be revoked or terminated without penalty therefore if so advised by the North Carolina Attorney General.
- 20.04. **Activities During Dispute Resolution Process**. Pending resolution of any Dispute under this Agreement, the Parties agree to fulfill their responsibilities in accordance with this Agreement, unless the Party voluntarily suspends its right to Transact Message Content in accordance with Section 19.02, is suspended in accordance with Section 19.03, or exercises its right to cease Transacting Message Content in accordance with Section 11.05(b).
- 20.05. **Implementation of Agreed Upon Resolution**. If, at any point during the Dispute Resolution Process, the Parties to the Dispute accept a proposed resolution of the Dispute, the Parties agree to implement the terms of the resolution in the agreed upon timeframe.
- 20.06. **Reservation of Rights**. If, following the Dispute Resolution Process, in the opinion of either Party, the mandatory Dispute Resolution Process failed to adequately resolve the Dispute, the Party or Parties may pursue any remedies available to it in a court of competent jurisdiction.

21. Publications.

- 21.01. Any Participant published or distributed reports, data, or other information that reference NC HIEA or NC HealthConnex shall contain a disclaimer statement to the following effect: Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the view and policies of NC HIEA.
- 21.02. NC HIEA may publish or arrange for the publication of information resulting from work carried out under this Agreement, and copyright any books, publications, films, or other copyrightable materials developed in the course of or resulting from work under this Agreement.

- 21.03. Upon Participant's publication of materials resulting from HIE Data, Participant shall furnish a minimum of two copies of reprints to NC HIEA.
- 22. **Notices**. All Notices to be made under this Agreement shall be given in writing to the appropriate Participant's representative at the address listed in Attachment 1, and shall be deemed given: (i) upon delivery, if personally delivered; (ii) upon the date indicated on the return receipt, when sent by the United States Postal Service Certified Mail, return receipt requested; and (iii) if by a form of electronic transmission, upon receipt when the Notice is directed to an electronic mail address listed on Attachment 1 and the sending electronic mail address receives confirmation of receipt by the electronic mail address.
- 23. **Medicare Record Access.** In compliance with 42 U.S.C. §1395x(v)(l)(I) and implementing regulations, NC HIEA agrees, until the expiration of four (4) years after the HIE Features are furnished under this Agreement, to allow the Secretary of the U.S. Department of Health and Human Services and the Comptroller General access to this Agreement, all applicable purchase orders, and to the books, documents and records of NC HIEA necessary to verify the nature and extent of the costs of this Agreement. NC HIEA further agrees that if any of the duties of this Agreement are carried out by a subcontractor of NC HIEA, such subcontract will contain a clause to the effect that, until the expiration of four (4) years after the HIE Features are furnished under such subcontract, the Secretary of the U.S. Department of Health and Human Services and the Comptroller General will have access to such subcontract and to the books, documents and records of the subcontractor necessary to verify the nature and extent of the costs of such subcontract. This Section 23 will survive the expiration or termination of this Agreement.

24. Miscellaneous/General.

- 24.01. Governing Law. This Agreement is made under and shall be governed and construed in accordance with the laws of the State of North Carolina. The place of this Agreement or purchase order, its situs and forum, shall be Wake County, North Carolina, where all matters, whether sounding in contract or in tort, relating to its validity, construction, interpretation and enforcement shall be determined. Participant agrees and submits, solely for matters relating to this Agreement, to the jurisdiction of the courts of the State of North Carolina, and stipulates that Wake County shall be the proper venue for all matters.
- 24.02. **Authority; No Conflict.** NC HIEA and Participant each represent and warrant to the other as follows: (i) that it is authorized to enter into this Agreement and to perform its obligations hereunder, and that the individual signatory executing this Agreement on its behalf is authorized, and has the capacity, to so execute this Agreement on its behalf, and (ii) that the execution of this Agreement by it and the performance of its obligations hereunder shall not conflict with or result in, with or without the passage of time or the giving of notice thereof, any breach, default or violation of any third party agreement to which it is bound, or any judgment, order or ruling of any court, administrative or regulatory agency or body, or arbitration award, to which it is bound or subject.
- 24.03. Amendment. This Agreement may be amended by agreement between the Parties. However, if the change is required for NC HIEA or Participants to comply with Applicable Law, NC HIEA may implement the change within a time period NC HIEA determines is appropriate under the circumstances. All Participants shall be required to sign an amendment adopted in accordance with the provisions of this Section or terminate participation in accordance with Section 19.02.
- 24.04. **Governmental Restrictions.** In the event any restrictions are imposed by governmental requirements that necessitate alteration of the performance of this Agreement, each Party shall provide written notification of the necessary alteration(s) to the other Party's Contract Administrator. NC HIEA reserves the right to accept any such alterations, including any price adjustments occasioned thereby, or to cancel the Agreement. NC HIEA may advise Participant of any restrictions or changes in specifications required by North Carolina legislation, rule or regulatory authority that require compliance by the State. In such event, Participant shall use its best efforts to comply with

- the required restrictions or changes. If compliance cannot be achieved by the date specified by NC HIEA, the Parties may terminate this Agreement.
- 24.05. **Inspection At Participant's Site**. Pursuant to N.C.G.S. §147-64.7, the State reserves the right to inspect, during Participant's regular business hours at a reasonable time, upon notice of not less than two (2) weeks, and at its own expense, the prospective equipment or other tangible goods, or the plant or other physical facilities of a prospective Participant prior to Agreement award, and during the Agreement term as necessary or proper to ensure conformance with the specifications or requirements and their adequacy and suitability for the proper and effective performance of the Agreement.
- 24.06. Audit, Access To Records. Pursuant to N.C.G.S. §147-64.7, the Agency, the State Auditor, appropriate federal officials, and their respective authorized employees or agents are authorized to examine all books, records, and accounts of the Participant insofar as they relate to transactions with any department, board, officer, commission, institution, or other agency of the State of North Carolina pursuant to this Agreement or to costs charged to this Agreement. The Participant shall retain any such books, records, and accounts for a minimum of three (3) years after the completion or termination of this Agreement. Additional audit or reporting requirements may be required by any Agency, if in the Agency's opinion, such requirement is imposed by federal or state law or regulation.
- 24.07. Assignment. No Party shall assign or transfer this Agreement, or any part thereof, without the express written consent of NC HIEA. Any assignment that does not comply with the requirements of this Section 24.07 shall be void and have no binding effect. NC HIEA, in its own discretion, will not unreasonably withhold its approval of an assignment in the context of a merger, acquisition, or sale of Participant.
- 24.08. **Conflicts Of Interest**. Participant acknowledges and represents that it has adopted policies governing conflicts of interest and ethics in the exercise of its authority, and its actions under this Agreement. Participant will review, disclose and employ its best efforts to resolve any anticipated or reported conflict of interest or issue involving its ethics policies during the performance of this Agreement.
- 24.09. **Survival**. The following provisions shall survive the termination of this Agreement for any reason: Sections 1, 2, 11.06(b), 11.06(c), 13, 15.07, 16, 18, 19.06, 20, 23, 24.01, 24.09, and 24.11.
- 24.10. **Waiver**. No failure or delay by any Participant in exercising its rights under this Agreement shall operate as a waiver of such rights, and no waiver of any right shall constitute a waiver of any prior, concurrent, or subsequent right.
- 24.11. **Entire Agreement**. This Agreement, together with all Attachments, sets forth the entire and only Agreement among the Parties relative to the subject matter hereof. This Participation Agreement replaces and supersedes all prior participation or subscription agreements between NC HIEA and Participant, and expresses the entire understanding of the Parties with respect to the transactions contemplated herein, and shall not be amended, modified or altered except pursuant to Section 24.03. Any representation, promise, or condition, whether oral or written, not incorporated herein, shall not be binding upon any Party.
- 24.12. **Validity of Provisions**. In the event that a court of competent jurisdiction shall hold any Section, or any part or portion of any Section of this Agreement, invalid, void or otherwise unenforceable, each and every remaining Section or part or portion thereof shall remain in full force and effect.
- 24.13. **Headings.** The headings throughout this Agreement are for reference purposes only, and the words contained therein may in no way be held to explain, modify, amplify, or aid in the interpretation or construction of meaning of the provisions of this Agreement. All references in this instrument to

- designated "Sections" and other subdivisions are to the designated Sections and other subdivisions of this Agreement. The words "herein," "hereof," "hereunder," and other words of similar import refer to this Agreement as a whole and not to any particular Section or other subdivision.
- 24.14. Relationship of the Participants. The Participants are independent contracting entities. Nothing in this Agreement shall be construed to create a partnership, agency relationship, or joint venture among the Parties. Neither NC HIEA nor any Participant shall have any authority to bind or make commitments on behalf of another Participant for any purpose, nor shall any such Party hold itself out as having such authority. No Participant shall be held liable for the acts or omissions of another Participant.
- 24.15. **Third-Party Beneficiaries**. With the exception of the Participants to this Agreement, there shall exist no right of any person to claim a beneficial interest in this Agreement or any rights occurring by virtue of this Agreement.
- 24.16. **Force Majeure.** A Participant shall not be deemed in violation of any provision of this Agreement if it is prevented from performing any of its obligations by reason of: (a) severe weather and storms; (b) earthquakes or other disruptive natural occurrences; (c) strikes or other labor unrest; (d) power failures; (e) nuclear or other civil or military emergencies; (f) terrorist attacks; (g) acts of legislative, judicial, executive, or administrative authorities; or (h) any other circumstances that are not within its reasonable control. This Section 24.16 shall not apply to obligations imposed under Applicable Law.
- 24.17. **Time Periods.** Any of the time periods specified in this Agreement may be changed pursuant to the mutual written consent of NC HIEA and the affected Participant(s).

This Agreement has been entered into and executed by officials duly authorized to bind their respective Parties as of the dates set forth underneath their signatures below.

Participant:	North Carolina Health Information Exchange		
Participant Organization Name:	Authority		
By:Authorized Signature	By:Authorized Signature		
Name:	Name:		
Title:	Title:		
Date:	Date:		

Addresses for Notice

Participant is required to provide information in the Primary Contact fields below unless otherwise noted. Pursuant to Section 22, Notifications will be sent to the contacts below concerning this Agreement, including the need for amendments. Pursuant to Section 22, Notifications will **not** be sent via facsimile; however, please feel free to provide this information.

Participant Address for Notice

	Primary Contact	Alternate Contact Not required
Name		
Title		
Organization		
Address		
City, State Zip		
Phone		
Fax (not required)		
E-mail		

NC HIEA Address for Notice

	Legal Contact for Notice	Technical Contact for Notice on Breaches Please contact SAS
Mailing Address	NC HIEA Attn: Legal Team 4101 Mail Service Center Raleigh, NC 27699-4101	Not Applicable
Phone	Phone: 919-754-6912	(919) 531-2700
Email	HIEALegal@NC.Gov	HIESupport@SAS.com

Please do not send any patient's individually identifying information or PHI through email.

Participant Staff Contact Information

Please provide contact information for the following staff members at your organization. Each field must be filled even if one person occupies more than one role. All fields must be completed or the processing of your Participation Agreement will be delayed.

Participant Account Administrator

Staff member who will be the point of contact for the NC HIEA for communications and credentialing NC HealthConnex users in your organization.

Name:
Position Title:
Email Address:
Phone Number:
Mailing Address:
Technical Services Contact
Staff member who will work with our technology vendor to build a connection from your organization to NC HealthConnex.
Name:
Position Title:
Email Address:
Phone Number:
Mailing Address:

Onboarding & Technical Specifications

Partic	apant Ba	ackground	1 Into	ormation		
1. Type of facility or system: Please select all that apply below.						
Hospital, Health System, or Regional HIE Ambulatory/ Outpatient Clinic	☐ La	boratory		Pharmacy		Other Please specify:
2. Participant Organization National Provider Identifier (NPI):			1		ı	
3. How many Participating Entities and/or facility locations does your organization have?		If more than one, please complete Attachment 4 to add all Entities and Locations				
4. Is your pharmacy a part of one or more the follow. If yes, please select all that apply and list the name						
☐ Health system						
☐ Regional HIE						
☐ Accountable Care Organization						
☐ Clinically Integrated Network						
Substance V	Use Diso	rder Trea	tmen	t Informatio	n	
5. Does your organization or any unit wit your organization provide Substance Use Disorder treatment?	☐ Yes [□ No)			
6. If yes to 65 does your organization fall under 42 C.F.R. Part 2? If unsure, please contact your legal counsel and visit the SAMHSA website at www.SAMHSA.gov		Yes No If Yes, you are prohibited from sending Part 2 data to NC HealthConnex pursuant to this Agreement and 42 C.F.R. Part 2.				
Pharmacy System Information Please discuss these questions with your Technical Services Contact						
7. Pharmacy System Vendor:	e question	is wiin youi	1 ecni	nicai services	Contac	i e e e e e e e e e e e e e e e e e e e
8. Pharmacy System Vendor Product & Version:						
9. Hosting Location:		☐ On-si	te			Cloud-based
				r on-site at cation		Other:
10. Pharmacy System Vendor Contact N	ame:					
11. Pharmacy System Vendor Contact Email:						
12. Pharmacy System Vendor Contact Phone Number:						

State Funding Information				
13. Do you accept and receive reimbursement from NC Medicaid?	☐ Yes ☐ No			
14. If yes to 13, do you receive reimbursement through a Managed Care Organization (MCO) or Local Management Entity (LME)?	☐ Yes ☐ No If yes, please specify:			
15. Do you accept and receive reimbursement from NC State Health Plan?	☐ Yes ☐ No			
16. Do you receive any other funds from the State of North Carolina for the provision of health care services, including grants?	☐ Yes ☐ No			
Family Educational Rights and Privacy Act Data				
20. Family Educational Rights and Privacy (FERPA):	My organization acknowledges that it is prohibited from disclosing FERPA data to the NC HIEA pursuant to this Agreement and Applicable Law and will not disclose any data subject to FERPA.			

Technical Specifications for Onboarding & Targeted Data Standards

- 1. **Pharmacy System.** The timeline for connecting your organization will depend on various factors, including the technical resources and capabilities of your Pharmacy System vendor, any work already undertaken by NC HIEA, SAS Institute ("SAS," our technology partner and subcontractor), and your Pharmacy System vendor to connect other Submitters, and resources available at your organization, NC HIEA, and SAS.
- 2. **Frequency of Submission.** Consistent with N.C.G.S. § 90-414.4(c), Submitter shall only be required to submit claims data once daily using the industry standardized formats identified herein but can establish near real time interface for reporting.

3. Targeted Data Standards

- a. NCPDP SCRIPT MedicationList. or NC HealthConnex Pharmacy Submission Delimited File. Submitters shall submit data elements from the NCPDP SCRIPT MedicationList transaction or the NC HealthConnex Pharmacy Submission Delimited File to NC HealthConnex to the extent possible for all data pertaining to Medicaid, State Health Plan, and State-funded health services provided by Submitter, as required by Applicable Law. Technical specifications for the flat file are included in the Onboarding Document.
- b. **Pharmacist eCare Plan**. In addition to the NCPDP SCRIPT MedicationList. or NC HealthConnex Pharmacy Submission Delimited File, Submitters may optionally submit the Pharmacist eCare Plan via Consolidated Clinical Data Architecture (C-CDA) for, at minimum, all data pertaining to Medicaid, State Health Plan, and State-funded health services provided by Submitter, as required by Applicable Law.
- c. If Submitter chooses to submit additional data related to non-State funded health care services in addition to what is required by law, Submitter should also submit the aforementioned data elements in 3(a) and 3(b) to the extent possible. Submitter may also submit data beyond the Targeted Data Standards for State-funded and non-State funded health care services.

Onboarding Process Summary

This summary presents a high-level overview of the process to connect your organization to NC HealthConnex. These steps are subject to change based on the availability of technical resources and functionality of your organization, your Pharmacy System vendor, and NC HIEA and SAS.

- 1. NC HIEA will notify SAS of the receipt of your organization's fully executed Participation Agreement and of the contact information you provided in Attachment 2. Please note: Failure to provide contact information in Attachment 2 will slow the processing of your agreement and your connection to NC HealthConnex.
- 2. SAS will contact your technical services contact person to verify the technical information requested above and to gather contact information for other technical partners your organization may have.
- 3. NC HIEA will contact your organization to discuss your organization's user training needs along with pharmacist, clinician, and patient education on NC HealthConnex.
- 4. The next steps depend on the type of data connection your organization will have to NC HealthConnex.
 - a. For a Transport Layer Security (TLS) connection:
 - i. Your organization must complete a TLS connection document.
 - ii. SAS and your technical resources will build a TLS connection to your EHR and will coordinate testing with your organization.
 - iii. Test Data will be sent to the Test/Stage environment. Any issues will be documented and resolved.
 - iv. Prior to sending data to the production environment, you will be required to provide User Acceptance Approval.
 - v. Data feeds will be promoted to the production environment when all Parties are mutually satisfied with the interface build. Your data will be validated by SAS in collaboration with your technical resource staff and any issues will be documented and resolved.
 - vi. NC HIEA will notify your organization that you have been successfully connected to NC HealthConnex and your Participant Account Administrator will be provided user credentials for the NC HealthConnex Clinical Portal. Training and education materials will be made available to your organization as well.
 - b. For a Batch Secure File Transport Protocol (SFTP) connection:
 - i. Your organization will be assigned to a SAS data connector vendor, who will work with your organization and/or EHR Vendor to build connection to NC HealthConnex. This will require installing software on your Pharmacy System.
 - ii. SAS will implement a daily secure batch transfer of data.
 - iii. The data connector vendor will test file transfers from your Pharmacy System to NC HealthConnex.
 - iv. Data will be sent to the Test/stage environment. Any issues will be troubleshooted.
 - v. Prior to sending data to the production environment, you will be required to provide User Acceptance Approval.
 - vi. Data will be sent to the production environment when all Parties are mutually satisfied with the interface build. Your data will be validated by SAS in collaboration with your technical resource staff. Any issues will be troubleshooted.
 - vii. NC HIEA will notify your organization that you have been successfully connected to NC HealthConnex and your Participant Account Administrator will be provided user credentials for the Clinical Portal, if needed. Training and education materials will be made available to your organization as well.
 - c. For connections built through hubs or interfaces to the NC HealthConnex environment by your Pharmacy System vendor, the Onboarding process will depend on your Pharmacy System

- vendor's system and capabilities, along with any previous work completed by NC HIEA and SAS with your Pharmacy System vendor.
- d. Similarly, if your organization will have Pharmacy Data integrated into your Pharmacy System, you may not require credentials to access the NC HealthConnex Clinical Portal. Further steps will need to be taken to build and test a bidirectional data connection to your Pharmacy System. You and your Pharmacy System vendor must collaborate with SAS to accomplish integration of Pharmacy Data into your Pharmacy System. This will require your organization to sign off after the integration is tested prior to production data flowing to your Pharmacy System.
- 5. Once your connection is established and you have access to NC HealthConnex, any technical issues your Authorized Users encounter should be directed to the SAS Help Desk at <a href="https://hittage.ncbi.nlm.nih.gov/Hitt

Participating Entities & Facility Locations

I. Is Participant executing the Agreement on behalf of one or more Participating I defined at Section 2.25.						
	Yes: No:					
II.	Provide the requested information regarding each Participating Entity as well as each of your organization's facility locations.					
	 If you have more than two Participating Entities, please click <u>here</u> to complete the Excel spreadsheet, labeled "Attachment 4," and submit it with this Agreement. 					
	 Include information for all facility locations that are part of your organization. Only provide the organization NPI for your Participating Entities or facilities; do not list individual provider NPIs. 					
	o Incomplete information on this Attachment will delay the process of your agreement.					
	 After Participant executes this Agreement, it is Participant's duty to provided updated, accurate information to the NC HIEA about facilities and Participating Entities. 					
1). Leg	al Facility Name:					
Facilit	NPI:					
Street	Address:					
City, S	tate, Zip:					
Count	·:					
Pharn	acy System Vendor/Version:					
<u>Facilit</u>	Type:					
Ambul	atory/Outpatient Clinic County Health Department Residential					
FQHC	Health System/Hospital Laboratory Free & Charitable Clinic Rural					
Health	Center Pharmacy Other (Please specify):					
State 1	unding Information (Check all that apply):					
NC Mo	dicaid MCO/LME NC State Health Plan					
Othon	tate of NC Funds for Health Care Services					

2). Legal Facility Name:		_	
Facility NPI:			
Street Address:			
City, State, Zip:			
County:			
Pharmacy System Vendor/Version:			
Facility Type:			
Ambulatory/Outpatient Clinic	County Health Department	Residential	
FQHC Health System/Hospital	Laboratory	Free & Charitable Clinic	Rural
Health Center Pharmacy	Other (Please specify):		
State Funding Information (Check all	that apply):		
NC Medicaid MCO/LME	NC State Health Plan	_	
Other State of NC Funds for Health Care	Services		
3). Legal Facility Name:Facility NPI:		_	
Street Address:			
City, State, Zip:			
County:			
Pharmacy System Vendor/Version:			
Facility Type:			
Ambulatory/Outpatient Clinic	County Health Department	Residential	
FQHC Health System/Hospital	Laboratory	Free & Charitable Clinic	Rural
Health Center Pharmacy	Other (Please specify):		
State Funding Information (Check all	that apply):		
NC Medicaid MCO/LME	NC State Health Plan	_	
Other State of NC Funds for Health Care	Services		

Business Associate Agreement

This Business Associate Agreement ("BAA") is made effective on the date of execution by both
parties of the Participation Agreement, by and between
(name of Participant) ("Covered Entity") and the North Carolina Health
Information Exchange Authority ("Business Associate") (collectively the "Parties").

1. BACKGROUND

- a. Covered Entity and Business Associate are parties to the Full Participation Agreement for Pharmacies for NC HealthConnex Access and Data Use (the "Participation Agreement"), whereby Business Associate agrees to perform certain services for or on behalf of Covered Entity.
- b. The relationship between Covered Entity and Business Associate is such that the Parties believe Business Associate is or may be a "business associate" within the meaning of the HIPAA Privacy Rule.
- c. The Parties enter into this Business Associate Addendum to the Participation Agreement with the intention of complying with the HIPAA Privacy Rule provision that a covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected heath information on its behalf, if the covered entity obtains satisfactory assurances that the business associate will appropriately safeguard the information.

2. **DEFINITIONS**

Unless some other meaning is clearly indicated by the context, the following terms shall have the following meaning in this BAA:

- a. "Electronic Protected Health Information" shall have the same meaning as the term "electronic protected health information" in 45 C.F.R. § 160.103.
- b. "HIPAA" means the Administrative Simplification Provisions, Sections 261 through 264, of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, as modified and amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Public Law 111-5.
- c. "Individual" shall have the same meaning as the term "individual" in 45 C.F.R. § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
- d. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164.
- e. "Protected Health Information" shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- f. "Required By Law" shall have the same meaning as the term "required by law" in 45 C.F.R. § 164.103.
- g. "Secretary" shall mean the Secretary of the United States Department of Health and Human Services or the person to whom the authority involved has been delegated.
- h. Unless otherwise defined in this BAA, terms used herein shall have the same meaning as those terms have in the Privacy Rule.

3. OBLIGATIONS OF BUSINESS ASSOCIATE

- a. Business Associate agrees to not use or disclose Protected Health Information other than as permitted or required by this BAA, the Participation Agreement, or as Required By Law.
- b. Business Associate agrees to use appropriate safeguards and comply, where applicable, with subpart C of 45 C.F.R. Part 164 with respect to electronic protected health information, to prevent use or disclosure of the Protected Health Information other than as provided for by this BAA.
- c. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this BAA.

- d. Business Associate agrees to report to Covered Entity any use or disclosure of the Protected Health Information not provided for by this BAA of which it becomes aware, including breaches of unsecured protected health information as required by 45 C.F.R. § 164.410.
- e. Business Associate agrees, in accordance with 45 C.F.R. § 164.502(e)(1) and § 164.308(b)(2), to ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of Business Associate agree to the same restrictions and conditions that apply to Business Associate with respect to such information.
- f. Business Associate agrees to make available protected health information as necessary to satisfy Covered Entity's obligations in accordance with 45 C.F.R. § 164.524.
- g. Business Associate agrees to make available Protected Health Information for amendment and incorporate any amendment(s) to Protected Health Information in accordance with 45 C.F.R. § 164.526.
- h. Unless otherwise prohibited by law, Business Associate agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from or created or received by Business Associate on behalf of, Covered Entity available to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- i. Business Associate agrees to make available the information required to provide an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528.

4. PERMITTED USES AND DISCLOSURES

- a. Except as otherwise limited in this BAA or by other applicable law or agreement, if the Participation Agreement permits, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Participation Agreement, provided that such use or disclosure:
 - 1) would not violate the Privacy Rule if done by Covered Entity; or
 - 2) would not violate the minimum necessary policies and procedures of the Covered Entity.
- b. Except as otherwise limited in this BAA or by other applicable law or agreements, if the Participation Agreement permits, Business Associate may disclose Protected Health Information for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate, provided that:
 - 1) the disclosures are Required By Law; or
 - Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.
- c. Except as otherwise limited in this BAA or by other applicable law or agreements, if the Participation Agreement permits, Business Associate may use Protected Health Information to provide data aggregation services to Covered Entity as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).
- d. Notwithstanding the foregoing provisions, Business Associate may not use or disclose Protected Health Information if the use or disclosure would violate any term of the Participation Agreement or other applicable law or agreements.

5. TERM AND TERMINATION

- a. **Term**. This BAA shall be effective as of the effective date stated above and shall terminate when the Participation Agreement terminates.
- b. **Termination for Cause**. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity may, at its option:
 - 1) Provide an opportunity for Business Associate to cure the breach or end the violation, and terminate this BAA and services provided by Business Associate, to the extent permissible by law, if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity;
 - 2) Immediately terminate this BAA and services provided by Business Associate, to the extent permissible by law; or
 - 3) If neither termination nor cure is feasible, report the violation to the Secretary as provided in the Privacy Rule.

c. Effect of Termination.

- 1) Except as provided in paragraph (2) of this section or in the Participation Agreement or by other applicable law or agreements, upon termination of this BAA and services provided by Business Associate, for any reason, Business Associate shall return or destroy all Protected Health Information received from Covered Entity or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
- 2) In the event that Business Associate determines that returning or destroying the Protected Health Information is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction not feasible. Business Associate shall extend the protections of this BAA to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

6. GENERAL TERMS AND CONDITIONS

- a. This BAA is part of the Participation Agreement.
- b. Except as provided in this BAA, all terms and conditions of the Participation Agreement shall remain in force and shall apply to this BAA as if set forth fully herein.
- c. In the event of a conflict in terms between this BAA and the Participation Agreement, the interpretation that is in accordance with the Privacy Rule shall prevail. In the event that a conflict then remains within this BAA, the BAA terms shall prevail so long as they are in accordance with the Privacy Rule.
- d. A breach of this BAA by Business Associate shall be considered sufficient basis for Covered Entity to terminate the Participation Agreement for cause.

IN WITNESS WHEREOF, the Parties have executed this Business Associate Agreement as of the day and year written above.

Covered Entity:	Business Associate:		
Participant Organization Name:	North Carolina Health Information Exchange Authority		
By:Authorized Signature	By:Authorized Signature		
Name:	Name:		
Title:			
Date:	Date:		

NC HIEA Policies and Procedures

The NC HIEA Policies are located here: https://hiea.nc.gov/providers/nc-hiea-policies

HIE Features

NC HIEA reserves the right to amend, terminate, or add additional HIE Features at any time. The availability of HIE Features to individual Participants depends on various factors, including the technical capabilities of NC HealthConnex and your organization. Please contact NC HIEA staff at https://hiea.nc.gov/nc-healthconnex-value-added-features.

Feature	Definition		
NC HealthConnex Clinical Portal	NC HIEA will provide Authorized Users access to the Clinical Portal. This Clinical Portal can be used to view the longitudinal patient record, set alerts and notifications, and to access other HIE Features.		
Provider Directory	NC HIEA will provide a Provider Directory to Authorized Users containing the secure email addresses of NC HealthConnex Participants and North Carolina providers participating in DirectTrust.		
Direct Secure Messaging	NC HIEA will provide Authorized Users with an ONC-compliant Direct Secure Messaging service, if desired. Each Authorized User will be provided with a unique address assigned in the NC HIEA Direct domain. Users will have the ability to append files containing Protected Health Information to their Direct messages.		
NC Immunization Registry	If available to Participant, NC HIEA will provide one way or bi-directional routing of patient immunization information through a common NC HealthConnex interface with the NC Immunization Registry.		
Electronic Laboratory Reporting	When available, hospitals can send electronic laboratory reports identifying required reportable communicable diseases and conditions to the Division Public Health.		
eHealth Exchange	When available, NC HIEA will enable Participants to query the eHealth Exchange participants through the Clinical Portal. Approved eHealth Exchange participants will be able to query NC HealthConnex, as well.		
	A connection with the Georgia Health Information Network is currently live, and a connection the U.S. Department of Veterans Affairs will be live in early 2018. Other eHealth Exchange participants will be added on an ongoing basis.		
Diseases Registries	A disease registry is a tool for tracking the clinical care and outcomes of a defined patient population. Data included in the registry can be important in assisting public health authorities and clinicians with appropriate preventive maintenance and disease management. Disease registries will extract relevant data from the NC HealthConnex system without any special effort required by Participants unless otherwise noted.		
	In June 2018, the NC HIEA and the Division of Public Health launched the Diabetes Registry. Relevant data submitted to NC HealthConnex is included in the Diabetes Registry. The NC HealthConnex Diabetes Registry supports attestation for Meaningful Use Stage 3 and Modified Stage 2 for eligible providers.		

Feature	Definition		
Clinical Notifications	This feature allows a participant to subscribe to alerts for a subset of their patient population to support care coordination. It is a file-based subscription service which provides notifications of admission and discharge events for a custom patient population. As an example, Clinical Notifications will allow a Participant to know when and where their selected patient(s) has an encounter at another participant's facility.		
Training	NC HIEA offers training for Clinical Portal use, DSM, and other HIE Features as determined by NC HIEA.		

Fee Schedule

This Fee Schedule is provided to Participant as part of this Participation Agreement and is effective on the date of execution by and between NC HIEA and Participant and any capitalized terms which appear herein shall have the same meaning as given in the Agreement unless otherwise noted.

NC HIEA – Bundled Services – Subscription Fees

Description	Standard Price	Fees
Full Participant Package	\$0.00	\$0.00

TOTAL FEES AND INVOICING

- Total subscription fees for this Fee Schedule are \$0.00.

eHealth Exchange Terms and Conditions

- 1.1 Participation by NC HIEA in the national eHealth Exchange, through execution of the DURSA, requires that NC HIEA replicate terms and policies found in the DURSA in NC HIEA Participation Agreements or governance policies. Participants shall comply with the following requirements, which shall apply solely when the parties, through NC HealthConnex, acquire, access, use, or Disclose Protected Health Information over the eHealth Exchange. Capitalized terms not defined in the Participation Agreement can be found in the DURSA or in the NC HIEA Privacy and Security Policy.
 - 1.1.1 **Permitted Purposes for Transacting Message Content.** The permitted purposes for which Participants or Participant Users may legitimately Transact Message Content over the eHealth Exchange through NC HealthConnex are as follows:
 - a. Treatment of the individual who is the subject of the Message;
 - b. Payment activities of the Health Care Provider for the individual who is the subject of the Message which includes, but is not limited to, Transacting Message Content in response to or to support a claim for reimbursement submitted by a Health Care Provider to a Health Plan;
 - c. Health Care Operations of either:
 - i. the Submitter if the Submitter is a Covered Entity;
 - ii. a Covered Entity if the Submitter is Transacting Message Content on behalf of such Covered Entity; or
 - the Recipient if (a) the Recipient is a Health Care Provider who has an established Treatment relationship with the individual who is the subject of the Message or the Recipient is Transacting Message Content on behalf of such Health Care Provider; and (b) the purpose of the Transaction is for those Health Care Operations listed in paragraphs (1) or (2) of the definition of Health Care Operations in 45 C.F.R. § 164.501 or health care fraud and abuse detection or compliance of such Health Care Provider:
 - d. Public health activities and reporting as permitted by Applicable Law, including the HIPAA Regulations at 45 C.F.R. § 164.512(b) or 164.514(e);
 - e. Any purpose to demonstrate meaningful use of certified electronic health record technology by the (i) Submitter, (ii) Recipient or (iii) Covered Entity on whose behalf the Submitter or the Recipient may properly Transact Message Content under this Agreement, provided that the purpose is not otherwise described in subsections 1-4 of this definition and the purpose is permitted by Applicable Law, including but not limited to the HIPAA regulations. "Meaningful use of certified electronic health record technology" shall have the meaning assigned to it in the regulations promulgated by the Department of Health and Human Services under the American Recovery and Reinvestment Act, Sections 4101 and 4102; and
 - f. Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual's personal representative as described in 45 C.F.R. § 164.502(g) of the HIPAA Regulations.
 - 1.1.2 Participants must Transact Message Content over the eHealth Exchange in accordance with the terms of the DURSA and must comply with the eHealth Exchange Performance and Service

- Specifications and the Operating Policies and Procedures. These policies are available at the eHealth Exchange website available here: https://ehealthexchange.org/how-to-join/
- 1.1.3 Except to the extent prohibited by Applicable Law, Participants shall provide information that is reasonably requested of it by NC HIEA or by the eHealth Exchange Coordinating Committee for the following purposes, as described in Section 4.03 of the Restatement I to the DURSA. Such purposes include for the Coordinating Committee: to determine whether Participant may exchange Protected Health Information over the eHealth Exchange; to receive and act upon reports of eHealth Exchange Breaches; to suspend or terminate the right of NC HIEA or Participant to exchange Protected Health Information over the eHealth Exchange; to resolve disputes pertaining to the eHealth Exchange; or to fulfill other responsibilities delegated to the Coordinating Committee. Participant shall not be required to disclose PHI to the Coordinating Committee in violation of Applicable Law. Any information other than Protected Health Information provided to the Coordinating Committee shall be labeled as confidential business information.
- 1.1.4 NC HIEA may voluntarily suspend or terminate, or the Coordinating Committee may suspend or terminate, NC HIEA's right to exchange Protected Health Information over the eHealth Exchange. If any such suspension or termination occurs, NC HIEA will notify Participant of the action as soon as reasonably possible. If an act or omission of Participant is the reason such suspension or termination occurs, Participant shall cooperate with NC HIEA to submit an appeal or a plan of correction to the Coordinating Committee, as applicable, as quickly as practicable.
- 1.2 **Required Alternative Dispute Resolution.** Participants shall submit any disputes related to their exchange of Protected Health Information over the eHealth Exchange to the non-binding Dispute Resolution Process as required by the DURSA and outlined below. If all of the parties involved in the dispute accept a proposed resolution of the dispute, Participant shall implement the terms of the resolution in the agreed upon time frame. Following the Dispute Resolution Process, Participant may pursue alternative remedies if it believes that the Dispute Resolution Process failed to adequately resolve the dispute.
 - 1.2.1 When a Dispute arises, a Participant shall send written Notice, in accordance with the Notice provision in the DURSA, to the other Participant(s) involved in the Dispute. The notice must contain a summary of the issue as well as a recommendation for resolution. The Participant must send a copy of the notice to the Dispute Resolution Subcommittee (see below) for informational purposes.
 - 1.2.2 Within thirty (30) calendar days of receiving the notice, the Participants are obligated to meet and confer with each other, at least once in good faith and at a mutually agreeable location (or by telephone), to try to reach resolution (the "Informal Conference"). If the Participants reach a resolution at the Informal Conference, they shall provide Notification to that effect to the Dispute Resolution Committee.
 - 1.2.3 If the Participants are unable to participate in an Informal Conference during the thirty (30) calendar day period or to reach resolution at the Informal Conference, they have ten (10) business days following the end of the thirty (30) calendar day period or the Informal Conference, respectively, in which to escalate the Dispute to the Dispute Resolution Subcommittee in writing.
 - a. The Dispute Resolution Subcommittee (the "Subcommittee") will be a five (5) member standing subcommittee of the Coordinating Committee. The Coordinating

Committee shall appoint each member of the Subcommittee for a definite term. The members must be representative of the Participants, have diverse skill sets, and be able to help facilitate and reach resolution on conflicts between the Participants. The Subcommittee must have access to legal counsel to advise it on the law relevant to matters before it.

- b. In addition to appointing the five (5) members of the Subcommittee, the Coordinating Committee must also appoint three (3) to five (5) alternates for the Subcommittee. Alternates will serve on the Subcommittee should any of the members have a conflict on a particular Dispute or in the event that a member(s) is unavailable. Subcommittee members are required to declare any conflicts in accordance with the Coordinating Committee's conflict of interest policy. Once a Subcommittee member declares a conflict, the remaining Subcommittee members shall decide amongst themselves whether such member must withdraw from the Subcommittee for the dispute in question.
- c. The Subcommittee must also have access to panels of subject matter experts, as identified by the Coordinating Committee, for a variety of topics that may be implicated by a Dispute. Each subject matter expert panel must have at least three (3) experts on it who will rotate as advisors to the Subcommittee.
- 1.2.4 Once a Participant escalates a Dispute to the Subcommittee, the Subcommittee will have thirty (30) calendar days in which to convene a meeting of the involved Participants ("Committee Meeting"). During this meeting, each Participant shall be able to present its version of the Dispute and any information that it believes is pertinent to the Subcommittee's decision.
- 1.2.5 The Subcommittee shall have the ability to request additional information from the Participants to help it make its determination. The Subcommittee, however, shall not have the authority to compel a response or the production of testimony or documents by the Participants. To the extent that the Participants do respond to requests of the Subcommittee by producing documents, Participants shall have the ability to mark the documents produced as "Confidential Participant Information" and the Subcommittee shall treat those documents in accordance with Section 16 of the DURSA.
- 1.2.6 The Subcommittee is encouraged to develop an appropriate and equitable resolution of each submitted Dispute, considering all available evidence, the goals of the Agreement and other relevant considerations. The Subcommittee must also have the authority to recommend sanctions for the breaching Participant. These sanctions include developing corrective action plans, suspension of participation rights, and termination of participation rights. The type of sanction will depend on the nature and severity of the breach.
- 1.2.7 Within fifteen (15) calendar days of the Subcommittee Meeting, the Subcommittee shall issue a written recommendation for resolution, including an explanation of the basis and rationale of its recommendation. If either Participant is dissatisfied with the Subcommittee's recommendation for resolution, it shall have five (5) business days in which to escalate the Dispute to the Coordinating Committee.
- 1.2.8 Within twenty (20) calendar days of receiving notice of escalation from a Participant, the Coordinating Committee shall review the Subcommittee's recommendation along with the information on which such recommendation was based and issue a final resolution. The Coordinating Committee may seek additional information from the Participants to aid its resolution of the Dispute.

- 1.2.9 Within seven (7) calendar days of receiving the final resolution from the Coordinating Committee, the Participants shall determine whether to accept or reject the resolution and so notify the Coordinating Committee.
- 1.2.10 The Coordinating Committee shall send a written summary of the resolution of the Dispute to all Participants. The summary will not identify the Participants involved, but will contain sufficient detail about the resolution to serve as an instructive resource for other Participants.
- 1.2.11 In no case shall a Participant be required to disclose PHI in violation of Applicable Law as part of its participation in the Dispute Resolution Process. The decision to not disclose PHI shall not be held against a Participant in the Dispute Resolution Process.

Technical Support

For more information on capitalized terms used in this Attachment but not defined in the Participation Agreement, please direct any questions to the SAS Technical Support Team.

Contacting the NC HealthConnex Technical Support Team

SAS NC HealthConnex Participant Account Administrator Assignment:

- The designated NC HealthConnex Participant Account Administrator (PAA) is recognized as the point of contact to utilize the SAS NC HealthConnex Technical Support Team and Help Desk.
- If the PAA chooses to add additional PAA that will coordinate with SAS, the existing PAA should communicate the additional PAA's name and contact information to the SAS NC HealthConnex Technical Support Team at HIEsupport@sas.com. Please also communicate any future changes to administration so that contact information will be kept up to date.
- All Authorized Users from your organization should communicate any questions they have about usage of NC HealthConnex to their PAA. The PAA should first try to answer the question for their Authorized Users. If they are unable to answer the question or has discovered an issue with the application, they should then direct questions, themselves, to the SAS NC HealthConnex Technical Support Team on behalf of their Authorized Users using one of the options below.

NC HealthConnex Technical Support Communication Options:

As a PAA, you have three options for communicating with our SAS NC HealthConnex Technical Support team:

SAS Email Support: <u>HIESupport@sas.com</u>

SAS Phone Support: (919) 531-2700

SAS Technical Support Form: http://support.sas.com/ctx/supportform/createForm

In the "Product" field, select "NC Health Information Exchange (HIE) - HealthConnex" All three options are tied closely with our customer issue tracking/ticketing systems, which ensures documentation of all issues and conversations, as well as providing timely responses and feedback. Details of how to use each option is listed below. If you have questions about the options reach out to us. We are happy to help you determine the best option for your organization.

Note: Please use only these three options. Avoid communication via individual email accounts and phone extensions. This ensures that the entire team knows about all issues submitted and that all team members have backup in case they are away from their desk or office. If you have been working with a specific Analyst on an issue, you will be forwarded to them so they may continue to assist you (or you may request that this occurs).

General Technical Support Hours of Operation:

- Monday through Friday 8:00 a.m. to 6:00 p.m. Eastern Time
- See details below for after-hours emergency and outage support

<u>Information you should provide</u> (regardless of the communication option you utilize)

- Contact name
- Contact email address
- Company name
- Company site number (it will start with "HIENCQ-#")
- Problem description
- Steps to reproduce and demonstrate the issue
- Results the user received (for example, if there was an error message what did it state, expected results were incorrect and how, etc.)
- Screen shots showing the error message as well as input prior to the error occurring
- Time, date and user experiencing the issue

- Client workstation details if appropriate (browser version, operating system, etc.)
- Is it an isolated incident or on going?
- IT contact name, if applicable

Severity Levels and Response Times:

Sev Level	Condition	Initial Follow-up*	Update Frequency
1	Critical: A critical SAS NC HealthConnex production system is down or does not function at all, and there is no circumvention or workaround for the problem; a significant number of users are affected, and a production business system is inoperable.	30 minutes	Every day
2	High Severity: A component of SAS NC HealthConnex is not performing, creating a significant operational impact. There is no circumvention/workaround for the problem.	1 hour	Every 2 business days**

Note: All Severity 1 and 2 issues occurring outside 8 am to 6 pm ET must be submitted <u>via</u> <u>phone</u> to guarantee response times listed.

3	Medium Severity: A component of SAS NC HealthConnex is not performing as documented; there are unexpected results; a workaround is available; there is moderate operational impact.	2 hours***	Every 3 business days
4	Low Severity: No operational impact to NC HealthConnex	1 day***	As agreed upon

^{*} For problems that are assigned to a Technical Support consultant, initial follow-up is defined as the time between when the problem is initially reported and the specialist contacts the customer. For problems that require further research by the consultant who initially received the problem, initial follow-up is defined as the time between the initial contact with the consultant and a follow-up call.

^{**} Follow-up as agreed upon by Customer Management and SAS Technical Support Management

^{***} Does not include weekend or other non-business days

Technical Support Communication Options Details: Email

Support:

Please send all email requests or issue communication to HIESupport@sas.com.

- Your email will go directly to the SAS NC HealthConnex Technical Support Team, a new issue Track will be created, and a *10-digit Track number* will be assigned/emailed to you. This 10-digit Track number is important and should be used in all on-going issue communication.
- You can update an existing Track by sending the *existing 10-digitTrack number in the subject line* to HIESupport@sas.com or by replying to the new Track confirmation email you receive. All members of the SAS NC HealthConnex support team are immediately notified when a Track is raised in this manner, as is the Analyst who is currently assisting you.
- Verify that any email SPAM software will not block our e-mail responses from <u>HIEsupport@sas.com</u>
- Please be detailed in your problem description by including the following information:
 - Steps to reproduce and demonstrate the issue
 - Results the user received (for example, if there was an error message what did it state, expected results were incorrect and how, etc.)?
 - Screen shots showing the error message as well as input prior to the error occurring
 - Time, date and user experiencing the issue
 - Client workstation details if appropriate (browser version, operating system, etc.)
 - Is it an isolated incident or on going?
- Please refrain from contacting the support team via direct email addresses. Our goal is to respond to you as quickly as possible and document all communication around a specific issue. If you email an Analyst directly, and that person is away or on vacation, you may experience delays in response times. Emailing the support address guarantees the email will be handled quickly and the details of your communication will be captured in the issue tracking system via the 10-digit Track number.

Note: All Severity 1 and 2 issues occurring outside 8 am to 6 pm ET must be submitted via phone to guarantee response times listed above.

Phone Support:

Please use the following phone number to call the SAS NC HealthConnex Technical Support Team: (919) 531-2700**press option "2"**

- You will then be prompted to enter "1" if you have a Track number (an existing issue) or enter "2" to speak with the operator (a new issue).
 - If this is an existing issue, please locate your SAS NC HealthConnex 10-digit Track number prior to making the call and provide it when prompted.
 - If this is a new issue, the Technical Support Analyst will provide a 10-digit issue Track number during the call (be sure to ask for one if you do not receive it!).
- If you entered "1" you will be routed to the Track owner during normal business hours (8 am 6 pm Eastern Time).
- A Technical Support Analyst will answer the call. Between 8:00 AM and 6:00 PM EST, ask to speak with a NC HealthConnex Technical Support Representative if they do not identify themselves as such. If after hours, and not an emergency, you can leave a message for technical support.

Note: All Severity 1 and 2 issues occurring outside 8 am to 6 pm ET must be submitted via phone to guarantee response times listed above.

SAS Technical Support Form:

Please submit your issue via the online form at http://support.sas.com/ctx/supportform/createForm

■ Before you proceed you should:

- Report urgent or critical problems by phone (see steps above)
- Verify that any email SPAM software will not block our e-mail responses from HIEsupport@sas.com.
- Enter the basic Information on the form to create a Track with SAS NC HealthConnex Technical Support. If you want to update an existing Track you can do so at http://support.sas.com/ctx/supportform/updateForm.
- Problem Description Be sure to include the following information:
 - Steps to reproduce and demonstrate the issue
 - Results the user received (for example, if there was an error message what did it state, expected results were incorrect and how, etc.)?
 - Screen shots showing the error message as well as input prior to the error occurring
 - Time, date and user experiencing the issue
 - Client workstation details if appropriate (browser version, operating system, etc.)
 - Is it an isolated incident or on going?
- After you supply the basic information, click "Next Page" to proceed. Otherwise click "Reset" to start over
- Shortly after you submit the form, you will receive an automatic e-mail that:
 - Confirms that you have submitted the form successfully
 - Provides the 10-digit Track number that has been assigned to your e-mail request. You will use this number to identify your issue moving forward.

Emergency Issues After-Hours

If your organization experiences a **total NC HealthConnex system or operational failure**; this is considered a critical Severity 1 or 2 issue (see definitions above).

- Please have the PAA and/or your IT point of contact validate that the outage/issue is occurring for all users and is not related to your facility's systems or infrastructure.
- If your contract states you have 24-hour support for Emergency Issues, please call the SAS phone support lines for assistance, **919-677-8008** -or- **800-727-0025**.
 - The SAS operator will forward you to a live, SAS Technical Support representative who will gather information to initiate a Track.
 - Please provide after-hours contact information for the main point of contact as well as the IT point of contact if applicable (for example, VPN /bi-directional feed usage Participants) and ensure both are available to help triage issues at that time (both are required for emergency tickets to be addressed after hours if you connect to the NC HealthConnex via VPN /bi-directional feed).
 - The SAS Technical Support representative will then contact an on-call SAS NC HealthConnex/SSOD Support Representative to work with your team.
 - On these occasions, you should expect a call back from a SAS NC HealthConnex/SSOD Support representative within 2 hours of your initial contact.
 - During off-hours support, you may be asked to provide your SAS Site Number.
- Because SAS cannot guarantee less than 24-hour response on problems tracked electronically, you should report Severity 1 or 2 problems **by phone**. If you chose to send an email or enter a Technical Support Form, your issue will be addressed the following business-day morning.

More information about SAS technical support services and policies can be found at http://support.sas.com/techsup/support.html.