



Roy Cooper
Governor

James A. Weaver
Secretary and State Chief Information Officer

**North Carolina Health Information Exchange Authority
Advisory Board Meeting**

MEETING MINUTES

Date: September 22, 2021
Time: 2:00 p.m. – 4:30 p.m.
Location: Virtual

Attendees:

Dr. Harriett Burns	Dee Jones
Christie Burris (NC HIEA Exec. Director)	James Weaver, NC DIT Secretary
John Correllus	Richard Pro
Dr. Jeff Ferranti (Chair)	Eric Snider (DIT Legal Counsel, NC HIEA)
Timothy Ferreira	Carolyn Spence
Jessie Tenenbaum (Sec. Cohen designee)	Dr. Donald Spencer
Donnette Herring	Dr. William G. Way

2:00 p.m. Welcome and Call to Order All Members & NC HIEA Staff
Meeting called to order by Chairman Ferranti at 2:06 p.m.

Housekeeping Items Chairman Ferranti

Chairman Ferranti reviewed the draft meeting minutes from the June 2021 meeting. Dr. Way moved to approve the draft minutes; Dee Jones seconded the motion, which passed unanimously.

Chairman Ferranti welcomed Tim Ferreira to review the Research Request Workgroup updates.

2:08 p.m. Research Request Work Group Update Tim Ferreira
Legal Considerations and Objectives

Ferreira outlined HIE requirements in the Statewide Health Information Exchange Act. The HIE shall develop protocols for data integrity, data sharing, data security, public compliance and business intelligence as defined in general statutes 143B-1381, and to the extent permitted by HIPPA it shall develop protocols for data sharing shall allow for the disclosure of data for academic research. Legal considerations for the Workgroup include:

- Prohibition on Commercial Purposes
- Participation Agreements and permitted purposes

- Opt Out of HIE
- HIPPA Privacy and Security Rules, and
- Information Blocking Regulations

Proposed Research Request Framework

Ferreira supplied an overview of the considerations that the Workgroup discussed as part of the framework development:

- Supporting expanded research activities within the NC HIEA's existing structural and financial means
- Sustain a consistent and efficient review process so that requests can be responded to in a way that is structurally fair and transparent
- Evaluate research requests with input from multiple stakeholders and perspectives
- Data security and protection must be assured
- Engage Advisory Board at appropriate levels to leverage insights and establish priorities
- Framework must utilize a scalable, flexible approach where researchers cover their costs

Next, Ferreira shared that the Workgroup's proposed framework objectives, key elements and workflow be guided by the principle that patient-centered care improves patient outcomes. The program should support academic research with a clear patient purpose to improve care, diagnosis, treatment, and establish an application period with a clearly defined schedule, requirements for requests, and notification of "award status," among other key objectives.

Academic Research and Commercialization of Data

Ferreira reviewed pre-decisional topics with the group.

- Characteristics of Academic research to include:
 - Requestor is affiliated/partnered with academic institution
 - Request has been approved by and IRB
 - Requestor agrees to publish finding, peer review.
 - Request has clear patient purpose to improve care, diagnosis, or treatment.
- Defining Commercialization of Data. A proposed operational definition for the term "Commercial Purposes" in the Act might encompass the following elements:
 - Access, use, redisclosure, and storage of clinical and demographic data sent to or through NC HealthConnex ("HIE data") beyond the purposes of supporting (i) treatment, payment, and health care operations as they are described in HIPAA.; (ii) population health; (iii) government programs; or (iv) academic research.

- Redisclosure or exchange of HIE Data with third-party organizations for the primary purposes of improving business operations, cost-cutting, or profit-seeking, without explicitly stated benefits to patients.
- Sale of HIE Data in exchange for money, other clinical or demographic data, services, or other items of value.
- NC HIEA and the Department of Information Technology reserve the right to conduct due diligence by examining data uses and proposed use cases in order to ensure legal compliance.

Implementation

Christie Burris reviewed framework implementation and asked for feedback to move forward on the framework proposal from the Board.

- Advisory Board research agenda
- Resource allocation, budget, fees
- Governance, policy updates, formal documents and internal protocols.
- Use Case Workgroup – define membership and protocols.
- Create operative documents
 - Data request application, application schedule, review rubric
 - Data use agreements
 - IRB and compliance review documents

Donette Herring asked what the Workgroup's recommendations are to protect the privacy and security of the data for research purposes.

Burris answered that the NC HIEA would be following requirements established under HIPAA as well as best practices of other federal and state entities that release data for research purposes.

Herring asked will part of the investment that is proposed create a secure data enclave so that data would be provided to researchers to use their tools and datasets to do particular research? And will datasets provided be deidentified data or will HIE provide identifiable data?

Burris responded that the Workgroup discussed several options. What can be done now is to provide a data extract for research or design interventions; however, over the long-term, GDAC envisions creating a space where researchers can bring datasets together. Such capabilities, however, are not part of the initial rollout; only deidentified data will be provided.

Harriette Burns asked what is the difference between what is being proposed now and what was in place before?

Burris answered that the Use Case Workgroup which was created previously brought use cases to the Advisory Board that are in development now. One being the Lincoln Project, and the other is the colorectal cancer registry use case. Some use cases are pulling data to design interventions that fall outside of the HIE normal business practices. One example is the HIE developing a stroke registry for Division of Public Health. In June of 2019 the Advisory Board decided operationalizing the request for data for research needed a more thoughtful process to meet all criteria to be a good data steward.

Chairman Ferranti asked what is the position on for profit entities, pharma companies, CROs or others that my request data of the HIE? Ferranti expressed the need for clear guidelines and guardrails around how the data is used. He also asked how the HIE plans to address or handle the volume of use case requests over the next year or so.

Burris responded that the goal is to entertain research requests that have a clear patient purpose to improve care, diagnosis, and treatment. The Workgroup expressed that defining that goal would serve as “north star” in terms of entertained requests, and that the requestor must be affiliated with an academic institution that conduct research and proposing the definition of commercial purposes will be those guardrails.

Tim Ferreira confirmed that the statute explicitly covers the prohibition against commercialization and the requirement for academic research.

Chairman Ferranti asked for clarification if a pharma company wanted to test a drug that would improve care, diagnosis and treatment came to the HIE to get the data, we would say no because there was a potential commercial benefit?

Burris responded that the decision was made that we would remove any clinical trial requests, outside of this framework. This is truly for academic research requests. Any pharma requests would not move through the workflow.

Burns asked if those pharma requests would be entertained?

Burris answered that later in the presentation she will share an example of a request from a clinical trial company that came to the HIE a couple of years ago.

Burns asked for clarity, that pharma companies and nonacademic public health endeavors are not going to go through the process?

Burris answered that in statute DHHS and public health already have a right to HIE data for various uses thus, they will not go through this proposed process.

Eric Snider shared that the manner in which the HIE entertains research requests from different kinds of requestors will come into greater focus as we build out the application forms and requirements.

Burriss stressed that the NC HIEA wants the Board to share specific questions and guidance for the Workgroup to take back so we can work toward a sound process to operationalize at a later date.

Dee Jones cautioned the group to make sure that requests are definable, specific and time limited. The SHP found that academic researchers try to make tangential research and want to use the same data for multiple uses. Jones encourages the group to put very specific requirements around requests.

Burns agreed and stressed that the appropriate technical infrastructure to support specific research projects rather than extracting data and letting it lead the HIE.

Ferranti also agreed with Jones that secondary uses are harder to track when data has left the premises.

Tim Ferreira suggested that the Workgroup help identify priorities but, that it may be premature to identify priorities at this point as we do not know that volume of type of requests that will present in this first application period. If volume is such that we need to identify priorities this could be managed separately.

Donette Herring recommended that if the NC HIEA didn't want to limit scope, then research projects should be more public-health related.

Dr. Way agreed with Herring to place some parameters around requests as we do not know what type of requests will present and we do not want to prevent requests that may be of great value. Public health is broad enough. It is clear that the Workgroup has done a lot of work but there is still more work to do and details to hash out about how the decision-making process will move forward. Way senses that the Board is not prepared to authorize requests at this point.

Chairman Ferranti thanked Tim and the informal Workgroup for presenting a model for the Board to think through and introduced Carolyn Spence to present the Legislative Report process.

2:58 p.m. Legislative Report Workgroup Update

Carolyn Spence

Carolyn Spence reviewed NCSL 2021-26 requirements:

on or before March 1, 2022, the NC HIEA Advisory Board shall submit to the Joint Legislative Oversight Committee on Health and Human Services recommendations

regarding appropriate features or actions to support enforcement of the Statewide Health Information Exchange Act contained in Article 29B of Chapter 90 of the General Statutes and the results of the outreach efforts in subsection (b) of this Section. Additionally, the HIEA shall contact each entity or provider identified and ascertain the status of the entity's or provider's effort to connect to the HIE. The HIEA shall share information with each provider or entity about the Statewide Health Information Exchange Act and how to connect to the HIE Network.

Spence gave a quick overview of goals and objectives and a six-month timeline of proposed activities of the NCSL 2021-26 informal workgroup, formed to support and inform the NC HIEA's efforts related to the report. Key actions to support internal HIEA work include:

- Identify and summarize current barriers to connection; examine available mitigation strategies
- Consider possible opportunities/consequences for providers/entities who fail to comply with the HIE Act, including how our organizations and others might facilitate/support their compliance
- Produce and provide advice regarding proposed recommendations to the NC HIEA Advisory Board by January and a comprehensive report to the General Assembly by March 1, 2022, that details:
 - NC providers/entities to whom the mandate applies, and who remain unconnected to date, including high-level metrics by provider type
 - Targeted outreach conducted with all unconnected providers, and their engagement statuses
 - Considerations and recommendations for incentives, penalties, and other consequences for failing to comply
 - Other recommendations to support provider/entity compliance with the HIE Act and boost HIE utility and usability
- Status of Analytics Project
 - Goals: determine individual providers and entities mandated to connect who remain not connected
 - Status: contract with SAS approved and work has begun

Dee Jones shared that when the State Health Plan (SHP) created its own network of providers, those providers are required to be connected to the HIE. Currently, there are approximately 30,000 SHP providers. A statement has been included in the SHP third party vendor contract requiring the vendor validate provider enrollment in NC HealthConnex.

Dr. Way asked where all payer claims database resides, where it is gathered?

Christie Burris answered that currently a database does not exist.

Chairman Ferranti thanked Carolyn for the update and released the group for a ten Minute break.

3:20 p.m. HIEA Update

Christie Burris

Christie Burris supplied a 3rd Quarter Operations update where she shared HITECH to MES funding progression path and next steps, future clinical data exchange within the future MES, and key stakeholders.

Burris highlighted NC DHHS and NC HIEA pandemic response efforts that included updates on the work to support CVMS-COVID Vaccine Management System and BIDP-Business Intelligence Data Platform.

Burris supplied a Data Quality Update and highlighted participant feedback. Participants appreciate the one-on-one calls to work on improving data submitted to the HIE. NC HIEA will continue to focus on hospitals for now but will expand into the ambulatory space.

Eric Snider introduced updates to NC HIEA Privacy and Security Policies-proposed revisions to conform to S.L. 2021-26. (draft proposals provided):

New State Law at G.S. 90-414.6 does *not* implicate Information Blocking § 171.103 Information blocking.

(a) Information blocking means a practice that—

(1) *Except as required by law or covered by an exception* set forth in subpart B or subpart C of this part, ***is likely to interfere with access, exchange, or use of electronic health information;*** and

(2) If conducted by a ... health information exchange, such ... exchange ***knows, or should know,*** that such ***practice is likely to interfere with,*** prevent, discourage ***access, exchange, or use*** of electronic health information.

Revise Privacy & Security Policies to conform to State Law

- **Section 15:** Individuals' Access to Electronic Health Information
 - Remove provisions concerning fulfillment of individual's requests
 - Addition: HIEA to provide educational materials and redirect individuals to their providers
- **Section 16:** Requests to Access, Exchange, and Use Electronic Health Information; Prohibition Against Information Blocking; Safe Harbors
 - Conforming edits: deletions of provisions regarding individuals' requests

- Addition: Compliance with G.S. 90-414.6 does not constitute information blocking

Snider asked the group to take time to review the draft policies provided and direct any feedback to the NC HIEA. Snider shared that the NC HIEA has posted information on the website as directed by session law to educate patients.

Burris informed the group that the NC HIEA is receiving additional use case requests for access to the HIE that fall outside of our current governance model. The NC HIEA has discussed expanding the participant base with a limited participation agreement. Burris supplied a few limited participation examples to the group:

- NC DHHS has a limited participation agreement with the HIE

Burris announced that SHIEC has merged with the National Network for Regional Healthcare Improvement and formed a new organization, Civitas Networks for Health. Burris highlighted advocacy efforts via submitted comment letters for:

- CMS Medicaid Cost Allocation-Request for OMB and CMS to update the cost allocation methodology to allow for Medicaid providers who will use technology vs. the number of beneficiaries, and that OMB waive cost allocation under the public health emergency for systems that support the state's public health response: CMS promoting interoperability requirements – clarifying the definition of bidirectional exchange to mean either 1) sending, receiving, incorporating or 2) using a portal or clinical view that is integrated into the EHR workflow as well as enforcing regulatory requirements that EHRs support bidirectional exchange without imposing additional fees; and finally to differentiate between state/regional HIEs and vendor driven networks.
- CMS-1751-P: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and other Changes to Part B payment policies
- Cures 2.0 - proposed the introduction and definition of health data utility to promoted interoperability in the public health space – leveraging state and regional HIEs who have the infrastructure in place will help modernize the reporting to public health systems as well as return data to providers.

Lastly, Burris supplied an overview of NC HealthConnex key metrics.

3:55 p.m. New Business

Chairman Ferranti

Chairman Ferranti announced the next order of business to elect a new Board Chairman and Vice Chairman. Chairman Ferranti moved to nominate Dr. William Way for Board Chairman, Tim Ferreira seconded. Next Chairman Ferranti asked

the group for additional nominations. Hearing no further nominations, Chairman Ferranti motioned for a roll call voice vote, Don Spencer seconded and Dr. Way was elected to Board Chairman by unanimous vote.

Next, Chairman Ferranti moved to nominate Donnette Herring for Board Vice Chairman, Carolyn Spence seconded. Next, Chairman Ferranti asked the Board for additional nominations. Hearing no further nominations, Chairman Ferranti motioned for a roll call voice vote, Dr. Way seconded and Donnette Herring was elected to Board Vice Chairman by unanimous vote.

Harriett Burns suggested a future informational presentation on Medicaid Managed Care rollout.

Chairman Ferranti expressed that he is incredibly grateful to have served as Board Chair for two terms. He thanked Christie Burris for her extraordinary leadership during a time of great growth for the HIE, and the NC HIEA staff who executed excellently against an ambitious vision.

4:16 p.m. Adjourn

Chairman Ferranti

Chairman Ferranti moved to adjourn the meeting at 4:16 p.m.

DocuSigned by:
Christie Burris 2/4/2022 | 8:16 AM EST
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