Addendum A

North Dakota Strategic and Operational Plan

Prepared by:

North Dakota Health Information Technology Advisory Committee

Submitted On:

March 17, 2011

Introduction:

North Dakota is pleased to submit this addendum to our revised strategic and operation plan dated December 6, 2011. This addendum addresses the items identified in the letter from Chris Muir, Program Manager, Office of State and Community Program dated March 7, 2011.

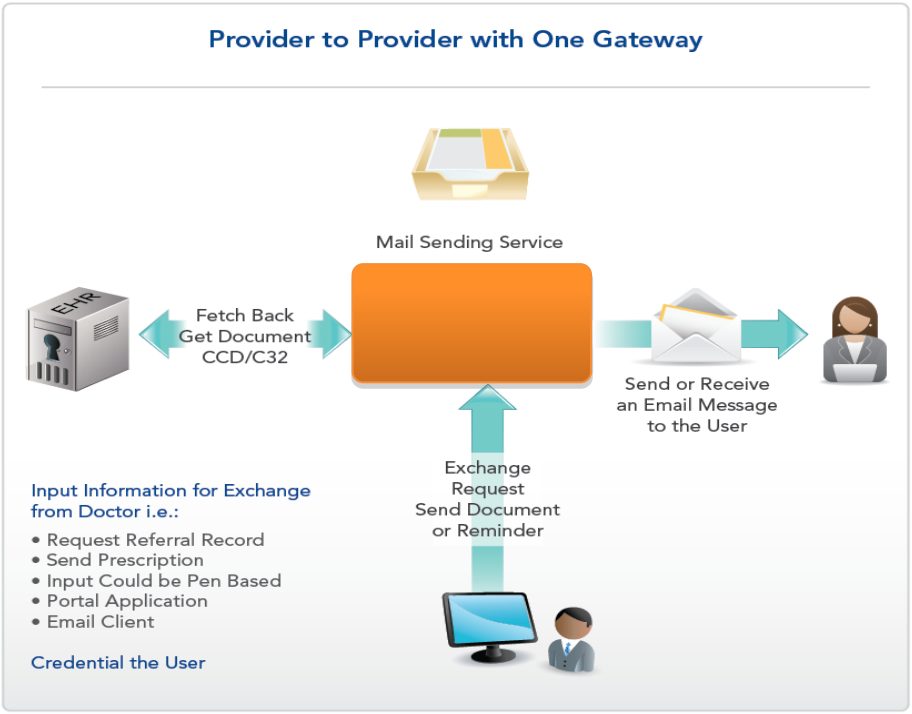
General:

It is ONC's position that before the more robust query based exchange is pursued with state HIE funding, provision must be made to allow all providers to achieve meaningful use through approaches that are achievable given the state culture, readiness, and current time constraints for phase I meaningful use. However, the gap filling efforts as outlined in the Program Information Notice dated July 6th, 2010 are required before North Dakota may use Cooperative Agreement funding to implement query based exchange between the six health care systems to the state HIE. Specifically, each eligible meaningful use provider in North Dakota must have at least one option for receiving structured lab results, sharing summary of care records and for e-Prescribing before the more robust, query-based exchange may be pursued.

North Dakota is in the middle of an RFP process for securing a vendor to build the HIE infrastructure. When the funding is approved by ONC, North Dakota intends to enter into negotiations with the selected vendor. For the purpose of this response, North Dakota asked all three of the leading vendors to describe how their solution would satisfy the expressed ONC concerns. All three vendors have responded and all three can satisfy the concerns expressed in the ONC letter. HITAC is committed to negotiate with the selected vendor to ensure all of the ONC concerns expressed in the letter are addressed. Therefore, this response will address ONC's concerns by describing the best solution for North Dakota based on the understanding of the approach suggested by each vendor.

North Dakota intends to use a phased approach for HIE implementation. HITAC will work with the selected vendor to design the project in 3 phases. The Phase 1 priority will be to make NHIN Direct functional across North Dakota. Phases 2 and 3 will expand upon this work and move thoughtfully towards building HIE across North Dakota.

The conceptual diagram below shows an example pattern where NHIN Exchange and Direct are combined to support provider-to-provider data exchange use-cases. In this use-case, a provider wants to send clinical documents in CCD/C32 format through the Exchange. NHIN Gateway queries and retrieves documents from an EHR system, packages/encrypts the documents along with metadata, attaches to an email, and sends the message to the end user.



Examples of the phasing proposed for North Dakota is described below.

Phase 1

1. Coordination with the REC and continued education and assessments of providers who want to use Direct for stage 1 Meaningful Use requirements
2. Development of coordinated REC and HIE outreach and education programs for providers
3. Development of HIE Direct Gateway (2011)
    - Integration with NHIN Exchange Gateway
    - Integration with North Dakota HIE portal (Web Email Client)
4. Launching projects with participating providers
    - Receipt of structured Lab Results
    - Availability of an e-Prescribing module
    - Sharing patient care summaries
5. Assessment of outcomes of the project
6. Continuous education and outreach, as well as coordination with REC on Direct beyond Phase 1

Phase 2

1. Identifying 2 of the hospital systems in North Dakota to pilot connections and the exchange of data
2. Working with the selected vendor to connect these pilot hospitals, their provider network and test the capability for the exchange of data
3. Monitor the exchange, evaluate the process, and learn as much as possible before connecting the remaining hospitals

4. Work with the selected vendor to redesign the HIE architecture to build off the lessons of the pilot program

Phase 3

1. Rollout the redesigned HIE architecture to the remaining hospitals
2. Work with the REC to provide education to providers and get them on the path to meaningful use
3. Connect the hospitals, providers, labs, pharmacies, state agencies and payers to the system
4. Implement the statewide exchange of health information

Leadership for ensuring these activities occur will be the responsibility of the Health Information Technology Advisory Committee (HITAC). This group is the governance structure for HIE in North Dakota. They will oversee the project and make sure North Dakota satisfies all ONC requirements.

E-Prescribing:

North Dakota's plan calls for e-prescribing options for all providers in Phase I. Please articulate how you will close the identified gap between readiness and use of e-prescribing, both for providers who are connected to health systems and those who are not. Also, describe the strategies to encourage the remaining pharmacies to e-prescribe; strategies may include policy, coordination, outreach, education, technical assistance, funding, etc.

The following statistics were identified in the assessment completed and reported in the North Dakota HIT Strategic and Operational plan:

> *"In examining the SureScripts report on e-Prescribing for 2009, it is reported that 86% of Pharmacies in North Dakota have activated e-Prescribing system. This represents an increase from 78% in 2008 and 57% in 2007. "*

The remaining 14% represent pharmacies in rural areas or those that have not turned on their e-prescribing capabilities. Based on the SureScripts data, the 14% equates to approximately 20 pharmacies who do not have pharmacy e-prescribing activated. It should be noted that a survey completed by the Pharmacy Association in 2010 indicated that some these pharmacies have e-prescribing functionality but have not turned it on because providers are not able to send e-prescriptions to them or because of the fees they are charged for e-prescribing. Therefore, the solution to increase e-prescribing will be two fold. One, determine why pharmacies are not capable of receiving electronic prescriptions and two; work to increase provider usage of EMR's.

For pharmacies, the HITAC, in conjunction with the Pharmacy Association and the Regional Extension Center (REC) will conduct an assessment to understand why pharmacies are not capable of e-prescribing. This information will be used to identify strategies and outreach activities for engaging the remaining North Dakota pharmacies that currently do not provide e-prescribing.

To increase the number of provider's e-prescribing, North Dakota will work closely with its REC

to identify the number of community providers who are actively implementing EMR's and identify any barriers that arise during the implementation. The HITAC and REC will work to remediate these barriers as they are identified. Additionally, HITAC will work with the Legislature to provide additional funding for providers to purchase EMR's and consider including an "EMR Lite" product in our HIE solution. These projects would include e-Prescribing functionality and should account for a rapid and significant increase in e-Prescribing throughout the state. Additionally, the HITAC will reach out to the major health systems to research why e-prescribing is not being widely used in their organizations. Information from this outreach will be used to develop a strategy to increase e-prescribing adoption. These strategies may include a targeted education program that describes the well-documented e-Prescribing benefits.

E-Prescribing is most valuable to providers when it gives them complete information including medication history. North Dakota anticipates adoption will increase consistently alongside of the additional HIE data services that have been outlined in the strategic/operational plan. Finally, there is pending legislation in North Dakota to study automating prior authorization requests. Once this is established, this could have the opportunity to increase the usage of e-prescribing.

Laboratory Integration

It is unclear about North Dakota's plans to engage laboratories. ONC requires additional detail on the gap filling strategies for enabling lab interoperability including a prioritization of labs and a rationale for the prioritization. Strategies may include policy, coordination, outreach, education, exchange services, technical assistance, funding, etc.

Labs in North Dakota are primarily part of a hospital system. When the hospitals connect, labs will be included as a part of the hospital EMR. Therefore, the majority of labs will connect automatically when their associated hospital connects. Additionally, there are very few independent labs in North Dakota, and these labs have been working on the electronic exchange of lab data one-to-one for several years and the state lab is working on making their system HL7 compliant. To maximize this electronic exchange, HITAC will use the process described below.

The electronic delivery of laboratory results is a multi-step process that begins with the creation of an order for a laboratory test. The test results can be sent directly to the clinician's EHR system or another clinical data system in support of the provisioning of historical results and results for non-ordering, providers of care. Providers of care may receive test results in the EHR system or another clinical data system or receive notification of the results (for later retrieval).

In order to further close the gap, HITAC will do the following:

- Develop a set of Core Services, which will include master provider and master facilities indexes. Entities participating in statewide HIE will be able to leverage these indexes to route labs to the appropriate destinations.
- Conduct a cost-benefit assessment of a statewide value-added service that transforms lab result messages to conform to the format, coding, and transport

requirements of the receiving EHR or public health agency and a component to route and transform laboratory orders as well as results.

- Participate with the REC, the State HIT Director, ONC NHIN development team, laboratories, providers, and EHR vendors in a coordinated effort to reduce the cost and complexity of electronic laboratory data exchange.
    - The goal of this effort is to establish secure, point-to-point transport of laboratory results, directly from labs to providers' EHRs, implementing Direct Project protocols and specifications.
    - The initial stage of this effort will be work by ONC and the REC to encourage vendors to adopt Direct Project specifications in providers' EHRs. Next, HITAC will work to encourage participation by hospital labs and other labs operating in the state for adoption and use of Direct Project specifications for secure transmission of lab results.
    - As part of the Core HIE Services being developed through Strategic and Operational Plan, the state will consider options for use of a Statewide Provider Directory to support look-up and/or routing functionality.
    - These efforts will be conducted in a manner that is consistent with advancing the HITAC vision and implementation as outlined in the North Dakota's State HIE Operational Plan.

Finance:

Following plan approval, an additional budget review will be required. Please make sure any changes in your timeline and plan are reflected in your budget.

HITAC clearly understands and commits to modify the budget within 90 days of ONC approval to reflect all changes made since submission of the plan to ONC.

Technical Infrastructure:

Please specify the options you have chosen to get to Phase I MU for all providers. ONC requires that you provide options for providers who need quick support to meet the Phase I requirements of meaningful use (MU). Describe how the individual provider, who is not connected to one the existing health systems, will connect to other providers, labs and pharmacy. Describe the messaging path between lab-to-provider and provider-to-provider. Be clear on your strategy to fill gaps and work in a targeted manner with REC and CAHs to achieve MU.

In addition to the information provided above, each of the vendors has a proprietary "EMR Lite" system to meet these requirements and each one of the vendors currently be considered has built and is supporting one or more active HIE's, that will satisfy these ONC concerns. HITAC is still studying its options but each vendor solution meets ONC requirements and the HITAC will select the vendor with the most cost effective solution that most closely satisfies ONC requirements.

Additionally, the following will be used to increase usage:

Provider Directory

The provider directory will be integrated into the overall solution architecture as an integrated component. The provider directory allows for the searching and routing of content of interest to selected providers. The directory is populated automatically via inspection of various clinical documents and messages, plus the provider to patient relationships is automatically determined. In addition, the provider directory can be initially populated via multiple federated data sources such as from the CMS's directory, the NLR provider export files, and other sources. HITAC will coordinate with Medicaid on developing and utilizing provider directories.

Certification Authority

Each vendor has proposed a process for Certification Authority that allows them to automate the otherwise problematic key management process. Specifically, as providers go through the technical enrollment process, they are automatically identity proofed, issued credentials, issued a private/public key pair, and provided with the tools needed to facilitate mutual authentication. The various configuration options allow a great level of detail for user access roles and privileges. Beyond demographics, configuration options include system user type, available system add-ons (e.g., eRx, lab ordering), user's workgroup, job category, prescription DEA and license numbers, user specialties, provider ID configurations (supports a wide range of entity IDs, including NPI), and more. With this diverse set of fields to define each user, HITAC can grant a wide variety of access levels to system data and functionality according to each user's functional role. For example, the NHIN certificate authority may be available, or vendors such as VeriSign and Network Solutions will also be capable of assigning certificates to the participating entities in an HIE network

Secure Messaging

Centralized messaging (as outlined in the vendor solutions shown above) will be provided within the selected HIE solution for secured messaging. The NHIN DIRECT option will be utilized for secure messaging to individuals who are outside of the HIE solution. HITAC is committed to selecting the option that provides maximum flexibility and access to authorized providers across the state.

For future phase activities, please provide as much detail as possible on the mechanisms planned to connect and integrate MMIS, payers, and existing health information exchanges to the state hub. The following are some of the questions that should be addressed.

- What services will be shared?

HITAC will select a vendor that can successfully provide the following shared services:

- Clinical Portal
- Patient Registry or Statewide Master Patient/Person Index (EMPI)
- Record Locator Service
- Provider Registry
- Organization/Facility Registry
- Terminology Translation Services to achieve semantic interoperability

- Consent Management
- Identity Management, Access, Authorization and Authentication
- Message Routing
- Public Health Reporting

Additionally, Medicaid currently utilizes Initiate as an EMPI. As we evaluate HIE vendors, we continue to evaluate how this asset can be utilized and maximized. Included with this evaluation is some additional functionality that MMIS is planning to add, including provider directories and vital record's birth and death records. Additionally, we will evaluate how Medicaid claims data can assist in creating a CCD or CCR populated with Medicaid claims' data using MMIS' current clinical decision support software for Medicaid professionals and beneficiaries, as well as using that same data to populate a viewer and produce best practices' reports with assistance from its current decision support vendor.

The first phase the North Dakota HIE implementation will focus on providing the centralized HIE core services that will meet all appropriate state and federal privacy and security standards. Local and enterprise HIEs and other associated providers (such as payers and existing IDN's) will utilize these core services in connecting to the State HIE solution.

The centralized HIE core services will provide a leadership role for health information exchange in North Dakota by facilitating HIE through convening, organizing, setting standards and requiring certification and compliance in order to connect. The state will initially focus on serving as a secure communications and message routing hub ensuring connectivity among multiple local and enterprise HIEs. The core Patient Registry or Statewide Master Patient/Person Index (EMPI) will ensure the integrity of its patient database by utilizing a Unique Identifier (UID) for each patient. This UID will be the basis for providers to match their patients with available records. The North Dakota Master Patient Index (MPI) may be initially populated from various sources including existing MPIs, State Driver's License Files, Medicaid Claims data, and Commercial Claims data.

The EMPI and the RLS are coordinated software applications. Based on registration records submitted to the MPI, the state HIE will be able to respond to on-line inquiries from HIEs and providers with a listing of providers that have previously registered the patient and therefore may be presumed to have health records available that are associated with that patient. The Provider Registry provide a centralized web-service that will be a directory of all physician practices, hospitals, long-term care providers, labs, etc.; including electronic routing information to allow messages to be routed to listed providers.

The requirements of applicable State statute and HIPAA regulations will ultimately define the approach to consent management. The patient's decision to opt-out will drive what information may be transmitted through the HIE, with direct implications for the design and operation of the infrastructure. The various aspects of consent management options will need to be considered in conjunction with the privacy and security policies adopted by the State.

Another one of the core services will provide authentication of individual users, provider systems, public health systems and local exchange systems that are authorized to access the

web services provided by the HIE. Local exchanges will be expected to manage authentication services for physician, hospital and other stakeholder systems connecting to the local exchange. Authentication standards will be required to match the standards established by ONC in order to allow participation in interstate data exchange via the NHIN. Once these standards are fully defined, the centralized core HIE services will enforce these standards in North Dakota using its ability to regulate connection to the HIE and other regulatory capabilities.

- How will you manage authentication and audit?

  Authentication

  Access will be controlled via role based user credential definitions. Data is only stored on private networks, behind Internet firewalls – not accessible from the Internet. The HIE will provide a user access control subsystem to enable login protection of local Agents and Nodes. Agents determine who needs the information based on programmed rules and distributes it directly to them. Information access is controlled through role-based authorization (at organizational and individual levels). The user must have a clinical relationship established with the patient in order to access any clinical data. A provider or staff member's level of access to a patient's clinical data is determined by their role in the organization and their relationship to the patient

  The access model relies upon a combination of controlled user access driven by rules and organizational roles which can be configured by department. Maintenance and oversight can be centralized or delegated to authorized departmental administrators.
  A variety of options are available to limit on the organizational level which patients and which types of data provider and staff users have access to. Access can be refined further on the individual user level, thus supporting personalization.
  Areas of access control include:

  - Which patients can be accessed
  - Data from what type of visit or encounter can be accessed
  - Whether VIP or employee information can be accessed
  - What types of clinical data are available to the user
  - What features of the application are available to the user

  Audit

  The selected solution will record all user activity e.g. login attempts, applications opened, user access to patient data, password and user profile changes, administrative and management functions etc. Examples of events captured are:

  - Patient (Select Patient, Open Document, View Patient Summary)
  - Administration (Start Up, Shut Down, Add/Remove Group from User, Add/Remove Group from Entry point)
  - Session, Server (Start Up, Shut Down)
  - User (User Authentication, Login, Logout, Account Status Change)
  - Clinical Portal Database (Import, Export, Merge)

  The details captured for each event are:

- Server - The server where the event took place
- Event Time - The time of the event
- Terminal ID - The unique identifier of the terminal where the request came from
- Session ID - The unique identifier of an individual user session
- User ID - The unique identifier of the user that initiated the request
- Event Source - The source that the audit event relates to, e.g. Clinical Portal
- Event Type - Type of audit event, which occurred e.g. Logon
- Message -Which contains more information about the audit event
- Event Result - Result of the audit event
- Patient Details - Key demographic details about the patient (PatientID, name, etc)
- Duration - Total duration of the audit event in milliseconds

- Do you plan to allow other health information service providers to provide exchange services?

HITAC will ensure the selected vendor supports multiple methods for exchanging information between provider systems thereby accommodating the various different HIE participants and their preferences. For many stakehpolders it is preferred that they leverage their own resources and capability to connect to the HIE, or to have a third party setup these exchange services. For these participating organizations, the selected vendor will provide the necessary documentation that will allow them to setup the exchange services and support them through the process. When completed, responsibility is assumed for the bidirectional exchange of information, including message mapping, coding and testing.

- What are the agreements that providers and health systems will be required to agree upon if they wish to use the state HIE exchange?

HITAC will evaluate and consider using some form of the DURSA agreement or modified version of that agreement or a "step down" agreement under which all providers and users will be required to agree to all HIPAA privacy and security requirements, and, as applicable, all Medicare and Medicaid privacy and security requirements, 42 C.F.R. part 2 requirements, and other applicable state and federal laws and other core requirements of the DURSA agreement. North Dakota may also consider adoption of the "Health Information Exchange Agreement: Private Entity Pilot" prepared for RTI and ONC (March 31, 2009) or a variation of that agreement

- Who will pay for, own, and maintain the edge servers?

HITAC will select a solution that offers flexibility such that the providers can choose to have the edge servers hosted at their facilities behind their firewalls, purchase the recommended hardware through their own purchasing organization and be maintained by or through the current maintenance agreement at their facilities. The vendors under considerations also offer hosting of the edge servers, which are purchased, maintained and supported by the vendor for a monthly hosting fee to the HIE. Lastly, the edge servers can be hosted, maintained and supported by a third party organization that the HIE chooses or by the State of North Dakota itself. Fees for the edge servers will

become part of the monthly fees determined in the HITAC sustainability plan currently under development.

Privacy and Security

Please clarify North Dakota's plans for connecting consent documentation in both interstate and intrastate health data exchange.

The North Dakota HIE will (1) require all providers, health plans, and other HIE users to sign the required HIE user privacy and security agreement (as outlined above); and (2) the North Dakota HIE plans to adopt the "NHIN Access Consent Policies Specification" or an appropriately modified NHIN Access Consent Policies Specification and process for using the electronic consent form. Use of this form will apply to both intrastate and intrastate transmission of ePHI/electronic health information. North Dakota plans to use only one standard consent form, i.e., North Dakota will use the same standard consent form for intrastate and interstate transmission of electronic health information. Further, North Dakota is a member of the Upper Midwest HIE Consortium a six-state group that is working to develop a common consent form (using the NHIN Access Consent Policies Specification v1.0, the Data Segmentation in EHI Exchange Policy Paper and other resources) that will be accepted by each member state for the interstate transmission of electronic health information.

North Dakota does not require consent for the disclosure of protected health information for treatment, payment, or health care operations for ordinary medical care received by adults. (At this time, North Dakota plans to use an opt out system for special requests of an individual to limit the disclosure of his or her health information.) North Dakota also does not require consent for disclosure related to treatment for mental illness or sexually transmitted diseases. Special consent requirements using the NHIN Access Consent Policies Specification consent standards will be established for treatment related to drug and alcohol abuse, treatment of minors aged 14 and over, and other special cases.