April 3, 2015

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

Attention: Public comments for Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0

The Minnesota e-Health Initiative is pleased to submit comments on the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0. We appreciate the work done to date by the ONC to continually identify and support critical actions for both private and public stakeholders to advance the nation towards a more connected, interoperable health IT infrastructure. Thank you for providing an opportunity to submit comments for your consideration. Should you have questions you may contact:

Kari Guida, MPH, MHI
Senior Health Informatician
Office of Health Information Technology, Minnesota Department of Health
kari.guida@state.mn.us

Sincerely,

Martin LaVenture, PhD, MPH
Director
Office of Health Information Technology, Minnesota Department of Health

Alan Abramson, PhD
Co-Chair, MN e-Health Advisory Committee
Chief Information Officer
HealthPartners

Bobbie McAdam
Co-Chair, MN e-Health Advisory Committee
Senior Director, Business Integration
Medica Health Plans

CC:
- Jeff Benning, CEO, Lab Interoperability Collaborative, Co-Chair, Minnesota Coordinated Response
- Greg Linden, Vice President, Information Services/Chief Information Officer, Stratis Health, Co-Chair, Minnesota Coordinated Response
- Diane Rydrych, Director, Division of Health Policy, Minnesota Department of Health

The Minnesota e-Health Initiative Response to Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Version 1.0

Introduction and Approach

The Minnesota e-Health Initiative ("the Initiative") is a public-private collaborative whose vision is to accelerate the adoption and use of health information technology in order to improve health care quality, increase patient safety, reduce health care costs and improve public health. A legislatively authorized statewide Advisory Committee guides the Initiative with 25 representatives from interested and affected stakeholders. The committee is co-chaired by Bobbie McAdam, Senior Director, Medica and Alan Abramson, Senior Vice President, HealthPartners. Details on the Initiative and the Advisory Committee are at http://www.health.state.mn.us/e-health.

This statewide coordinated response to the request for public comment invited multiple stakeholders from the Minnesota health and healthcare system to participate in two conference calls and submit written comments. Jeff Benning, Lab Interoperability Cooperative, and Greg Linden, Stratis Health provided leadership as co-chairs of the response and the Minnesota Department of Health, Office of Health Information Technology coordinated the work.

The Initiative recognizes the value in developing critical actions for stakeholders that will advance the nation towards an interoperable HIT ecosystem, advance research, and achieve a learning health system. However, we identified areas needing more clarity or action in the comments below. The Initiative is providing feedback three ways: general comments, feedback on critical actions by table, and response to specific questions. We strongly encourage consideration of these comments.

General Comments

- The roadmap is an important step forward in advancing interoperability and it captures a number of key critical actions necessary for interoperability.
- We support the principles of the learning health system, person-centered care, and social determinants of health.
- We support use of the foundational building blocks, learning health system requirements and critical actions useful. However, we find the various framework descriptions and focus areas in the introduction confusing. For example, Figure 2 (pg. 15) does not align logically with the four priority areas (pgs. 11-14).
- We support the focus of health information exchange across the continuum of care. However, our experience shows us we need more resources to accelerate the adoption and use health information exchange in settings beyond clinics and hospitals such as behavioral health, local public health, long-term and post-acute care, and social services. In addition, there needs to be more evaluation and applied research d in settings beyond clinics and hospitals.
- We support the addition of social determinants as essential in the transition to population health management and accountable care. We perceive, however, a rather large gap in connecting these social determinants to the critical actions listed. Much more work needs to be done in articulating these connections, harmonizing standards for measures, and in developing methods for appropriate data collection and sharing.

- We strongly encourage the addition of "e-health in all policies" to the Interoperability Roadmap and all work of the ONC. Similar to health in all policies, e-health needs to be a critical component of all federal and state programs' strategic plans. This means programs consider e-health in all decision-making across sectors and policy areas. This should be an idea enforced by the national interoperability roadmap as well as state interoperability roadmaps.

Feedback on Critical Actions by Table

Table 1: Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability

- For the actions in Table 1 (and the entire framework) to be successful, it will be necessary to engage providers across the continuum of care such as dentists, local public health, social services, chiropractic offices, long-term and post-acute care, and behavioral health. This may require the ONC and partners to employ different strategies for communication and engagement, including building upon or expanding the policy levers in Appendix A. Also note that providers from across the continuum of care might include those who many not be defined as "providers" under federal legislation. Steps should be taken to address this issue.
- We support federal agencies aligning their policies for interoperability with the nationwide governance framework but have concerns about getting the VA, DOD, IHS, CDC, and CMS to achieve this in a timely manner and without disrupting care and service delivery.
- Future Meaningful Use stages can be policy levers to achieve the objectives of Table 1 but more detail is needed to clarify how that will happen and how the process will engage current non-eligible professionals.
- Providing governance over a diverse community is complex. More clarity is needed to address issues including but not limited to transport mechanism, standardized agreements, and the role states would play.

Table 2: Critical Actions for a Supportive Business and Regulatory Environment that Encourages Interoperability

- It is currently difficult for EHR and other HIT vendors to "keep up" with state and federal regulations when state regulations are not aligned with the federal or other state regulations. Therefore, each state having an interoperability roadmap without clear direction from and alignment with the federal government is a huge burden on EHR and HIT vendors and may not lead to nationwide interoperability. What steps will be taken to assure there are not 50+ interoperability roadmaps with 50+ state standards developed/endorsed?
- The lack of alignment between the various arms/programs of the federal government around e-health and interoperability is also a large burden for EHR and other HIT vendors, states, and providers.
- The roadmap should include critical actions to reduce the variability between states. The national roadmap should cover 80% of what states needs allowing the other 20% for the states to best meet their needs.
- Development and implementation of a state interoperability roadmap will require collaboration of multiple state agencies including health, human services, corrections, education and more. This activity will require resources, state leadership and support, and possible state legislation to develop and implement. This is a large task, funding from the ONC or partners will be necessary.

- The state interoperability roadmap must have a strong and scientifically supported population health component – taking into consideration providers across the continuum of care, the learning the system, and social determinants of health/health equity.
- Funds and technical assistance are need for states to create an interoperability roadmap. Minnesota has started some of these discussions and found the amount of effort and stakeholders to engage to be a very significant activity.
- For states to implement their to-be-developed interoperability roadmaps, RECs and others will need to provide technical assistance and pricing based on non-medical models. For example, using the REC with its current pricing based on the medical model is prohibitive for the dental environment.

Table 3: Critical Actions for Individuals are Empowered, Active Partners in Their Health and Health Care

- Throughout C1, "should demand" should be "should expect". We cannot require consumers to do something, but we can work towards education leading to "should expect" and we can provide education and support on how to do that.
- We do not have the ability to measure "a majority of individuals and caregivers should demand access to their electronic health information in a format they can use to manage their health or that of others." In addition, not everyone needs access to their health information, has the ability (internet/mobile devices) to access it, or the desire/preference to access it.
- The consumer access needs to be designed for mobile devices.
- State and federal policy needs to fit what consumers want (control and granularity) before we can get the next level of consumers having access to what they want. For example, not all the information is currently available or in a useful/readable format in patient portals.
- There needs to be improved standards to achieve much of Table 3.
- Use of patient generated data and other consumer focused should consider more than just clinics and hospitals. For examples, what consumer tools and patient generated data would dental providers needed?

Table 4: Critical Actions for Care Providers Partner with Individuals to Deliver High Value Care

- For Category D4, the workflows are very clinical and do not include care and data from across the continuum of care nor seem focused enough on health transformation or care coordination. Critical Action 1, we recommend including workflows for public health reporting, population health, ADT (admit, discharge, transfer has gained traction across the continuum of care in Minnesota), and lab ordering and results. Is closed loop transition of care the same as closed loop referral? If not, closed loop referral needs to be added, as it is just as important as transfer of care.
- For Category D4, Critical Action 2, more work is needed to develop and test standards and the process of incorporating information from patient-owned devices. We recommend placing that action into 2021-2024. This Critical Action is also extremely clinically focused, excluding providers, care, and data from across the continuum of care.

Table 5: Critical Actions for Ubiquitous, Secure Network Infrastructure

- The critical actions in Table 5, 2015-2017, are not a realistic timeframe. Each critical action needs to be broken into steps for 2015-2017, 2018-2020, and 2021-2024. There needs to be work to develop how to achieve those critical actions (implementation plan) and then time and milestones to achieve the implementation plan. The implementation plan and the critical actions need to include continuous quality improvement, including sharing and learning from breaches, and evaluation components as well as a strategy for addressing urgent issues. In addition, the concept of a learning health system is missing from this table. What implications do these critical actions have on the learning health system?
- There is the potential that these critical actions may create unintentional delays in product releases. What can be done to eliminate or limit this problem?
- These critical actions are important but there is a need for more engagement/communication with the EHR and HIT vendor community. This issue needs to be addressed to assure that the critical actions and associated implications are part of the EHR and HIT vendor roadmaps/strategic planning.

Table 6: Critical Actions for Verifiable Identity and Authentication of All Participants

- For Category F1, Critical Action #1, more clarity is needed on who is included in "all roles". If the consumer is included, this can get very expensive. In addition, there needs to be acknowledgement of the cost of this activity. Most of the critical actions seem to be goal statements. To make this roadmap useable, the goal statements need to be broken into concrete, achievable steps over the next 10 years.
- For Category F2, the timeline is not realistic. In 2015-2017, the standards need to be developed and piloted (provide funding for this activity) with ongoing development, piloting and consensus building in 2018-2020. The last part of 2018-2020 can include training and implementation with rollout in 2021-2024. Also, need to consider how mobile technology will change in 10 years to assure we are making standards for the future, not yesterday.

Table 7: Critical Actions for Consistent Representation of Permission to Disclose Identifiable Health Information

- Table 7 leads to new thinking on privacy and disclosure.
- It is important to use HIPAA as an enabler of health information exchange instead of as a barrier. To do this requires education across the continuum of care and needs to include health plans and states and federal agencies.
- There is a need to acknowledge that some states, such as Minnesota, have stricter laws on privacy and disclosure. This needs to be taken into consideration in each of the critical actions.
- The technology, state and federal policies and laws, and workflows may not be there to manage granular choice.
- To achieve the critical actions in Table 7, states will need to involve multiple state agencies including health, human services, corrections, and education and their related regulations, policies and workflows that related to consent, sensitive health information, and security. This activity needs to be identified and incorporated into the shared nationwide roadmap to assure care across the continuum.

- The critical actions throughout the table need to address public health reporting and other reporting to state agencies.
- Alignment of patient consent across states needs to be addressed for persons and providers that seek and treat in different states.

Table 8: Critical Actions for Consistent Representation of Authorization to Access Date or Services

- Table 8 needs clarity in the overall intent (title of table) and how "deep" the critical actions are expected to go. To provide the clarity, more input from privacy and security experts is recommended.
- The workshops and listening sessions needs to include a broad representation from all stakeholders from states with a variety of policies and laws on health information exchange, data sharing, and authorization.
- Ongoing work is needed to identify and implement policies and best practices that encourage interoperability while maintaining privacy for the person.

Table 9: Critical Actions for Stakeholder Assurance that Health IT is Interoperable

- We strongly support expanding the certification program to include additional providers such as long-term and post-acute care, behavioral health, local public health, social services, pharmacies, and others. The HIT certification should be aligned and collaborate with other accreditation and certification programs related to the settings. For example, criteria for local health department accreditation by the Public Health Accreditation Board should be adoption and use of a certified EHR.
- This Table would benefit greatly from the engagement and feedback from EHR and HIT vendor community to develop more concrete steps and a more realistic timeline.
- The critical actions need more clarity how to create tools that align with recommended standards and what can be developed to address barriers to interoperability today.
- Minnesota had discussion and did not reach consensus on the implications on SDOs and a new role of testing tools. The discussion included should they start being involved in testing tools, how would it fit with their business model, and is it appropriated (a possible loss of balanced oversight).

Table 10: Critical Actions for Consistent Data Formats and Semantics

- The critical actions in Table 10 are hard work. Many of the critical actions need to be broken into steps and spread across the next 10 years.
- There needs to be more clarity on how to build upon existing efforts. There are numerous standards currently. There needs to be a process on how areas needing standards or standards needing work are identified and prioritized.
- There needs to be more recognition and action on how to implement standards we have in place today and how to choose when there are multiple "best available".

Table 11: Critical Actions for Secure, Standard Services

- There needs to be more clarity around the definition and defined role of public APIs.

- The development of public APIs is a huge undertaking. We recommend this category and critical actions continue into 2018-2020 and 2021-2024.
- The ONC and partners will need to develop policy levers or incentives for EHR and HIT vendors to use the public APIs.
- The critical actions needs more detail on the who, how, and when. In addition, an explanation of how this will happen in concert with the FHIR work is needed.
- Providing more detail on the roles and expectations of SDOs going forward in this work will provide more clarity in this table.

Table 12: Critical Actions for Consistent, Secure Transport Techniques

- Table 12, specifically Categories L2 – L3, is sending a clear message to use Direct. The implications of this have not been fully articulated and no strategies to address unintended consequences have been included or even a process to mitigate issues. To address unintended consequences and new and emerging technology, a process should be established to address these issues and to assure core functionalities are maintained.
- Expecting a critical mass of any non-eligible professional and dentists and chiropractic offices to use Direct by 2017 is unrealistic. These settings are still trying to make the case for adoption and use of EHRs, trying to get EHR vendors to develop tools that meet their settings needs and specific standards. We suggest moving the target out to 2018-2020 for non-eligible providers and making the list of providers more complete. For example, in Minnesota 2018-2020 is reasonable for local public health, nursing homes, and behavioral health to have achieved critical mass for a few transactions. Other settings such as home care and social services would be in 2021-2024 and may only need one or two transactions such as ADT and referrals.
- For non-eligible providers and dentists, there should be incentive for early adopters, which will allow the ONC and states to learn from the early adopters and develop best practice. This should allow for better investment of funds in future Direct activities.
- The steps and resources for public health agencies to converge on the use of standardized web services are complex and will take more resources and time (2018-2020). It should be noted that other state agencies should also move in this direction including human services, corrections, and education. Clarity is needed regarding whether this refers to state public health agencies or local public health.
- Consumer's ability to transport their health information (Category L1, Critical Action 3) should be moved 2018-2020 or 2021-2024 especially if this includes data from non-eligible professionals.

Table 13: Critical Actions for Accurate Individual Data Matching

- The critical actions in Table 13 need to be reviewed and commented on by those in immunization registries as they have more than 15 years of experience with the policy, workflow, and technical issues.
- The critical actions need to address policy, workflow, and technical issues to assure the ability to find and choose an individual uniquely.
- The section provides a good description of the problem but is weak in actually articulating what is going to happen.
- This is an important topic and more clarity and learning is needed resolve the issues related to it.

- We strongly encourage a process to identify and share processes and best practices for individual data matching.

Table 14: Critical Actions for Reliable Resource Location

- It is necessary to prioritize what resources are needed first.
- More detail and specific steps are needed to explain the how and to create a more realistic timeline as the current one is too aggressive.

Table 15: Measurement Actions

Minnesota has measured e-health progress for several years. Our biggest lesson has been what gets measured, gets down. It is necessary to consider this while working on measurement actions. In addition, Minnesota has many lessons learned to share with ONC and other states. Information on these assessment activities is at http://www.health.state.mn.us/e-health/assessment.html. Karen Soderberg from the Office of Health IT within the Minnesota Department of Health (Karen.soderberg@state.mn.us) will assist ONC on these matters. In brief, we recommend that the measurement activities:

1. Establish and follow a framework that will accommodate changes in technology and HIE practices over time. For example, MN uses the adopt-utilize-interoperate framework, which will eventually evolve to include advance tools such as data analytics. This framework is easily applied across health care settings regardless of the services provided or their stage of adoption.
    - Measure not only system capability (e.g., EHR functionality) but also capacity (e.g., how and how much providers use the functionality).
    - Measure data quality (e.g., how data are captured in the EHR by providers)

2. Consider assessing HIE by use cases. HIE is difficult to measure using surveys. In MN we are experimenting with measuring use-cases; e.g., what types of transactions (e.g., lab result, care summary) and with whom (e.g., unaffiliated clinics, LTPAC; behavioral health). We also measure both the need to exchange with each type of provider and their ability to do so electronically.
    - MN is also planning to use data from HIE service providers and MDH public health reporting to inform what organizations are using HIE and what standards are in use.

3. Establish methodological best practice recommendations to support states/localities/associations in doing their own measurement along the nationally recommended framework. Some key practices include:
    - Recommend a standard unit of analysis (practice vs provider). Recognize that electronic systems tend to be implemented at the organizational level, not necessarily the provider or site.
    - Recommend how to identify the universe. In Minnesota, we only know this for hospitals and local public health. We have an estimate of the number of clinics. In order to best understand the results it is important to establish a definition of the universe and be able to enumerate and characterize the members.
    - Describe how to measure across non-clinic and non-hospital settings.
    - Describe who within the organization should respond.
    - Offer methods for optimizing response rate, such as engaging the support of provider associations.

- Offer best practices on survey administration, including data collection methods, policies and procedures.

4. Accommodate state-level policy differences; e.g., consent, HIE. States are unique; and regions within states are unique. This is where a common framework can support "modular" sets of questions that can be applied across states. For example, measuring how MN providers use an HIE service provider is much different from a state that has a centralized exchange.

5. Make data available in a timely manner for use by states and other partners. The data should be available at a state level.

6. Identify measurement for consumers/person use of e-health such as patient portals, individual developed data, and other HIT. This will provide more information to assist in the standards development needed.

ONC Specific Questions

1. General

1.1 Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term? Why or why not?

- Most of the critical actions will improve interoperability. This is a broad framework. Some of the critical actions will need more detail to assure the nation moves together in the same direction. Please see the comments related to each table for comments on any table specific gaps, the timing and stakeholders' issues.
- There is support for the four critical actions for near term wins (pgs. 11-14).

1.2 Describe any gaps that need to be addressed.

- We support the addition of social determinants as essential in the transition to population health management and accountable care. We perceive, however, a rather large gap in connecting these social determinants to the critical actions listed. Much more work needs to be done in articulating these connections, of harmonizing standards for measures, and in developing methods for appropriate data collection and sharing of data.
- We strongly encourage the addition of "e-health in all policies". Similar to health in all policies, e-health needs to be a critical component of all federal and state programs. This means programs consider e-health in all decision-making across sectors and policy areas. This should be an idea enforced by the national interoperability roadmap as well as state interoperability roadmaps.
- The roadmap is missing an opportunity build off the pharmacist/pharmacies role in engaging consumers, counseling and patient management, and medication therapy management.
- Throughout the roadmap, the issues and considerations of dentistry are largely ignored. We recommend working with the dental association to address issues and identify policy levers outside of Medicaid and Medicare as very little public funding goes into dentistry.

1.3 Is the timing of specific actions appropriate? Why or why not?

- For many of the tables, we identified the need to break the actions into steps and spread across the 10-year timeline. We found most of the critical actions would be just right for early adopters, a

challenge for those in the middle, and a stretch that many be impossible to achieve for the laggards.

1.4 Are the right actors/stakeholders associated with critical actions? If not, please comment.

- Many of these actions involve EHR and HIT vendors, feedback from this community is crucial for a realistic roadmap.
- It is necessary to continue to engage non-eligible professionals and associated issues throughout the roadmap.

2. Priority Use Cases

2.1 Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization. Please submit three priority use cases that should inform priorities for the development of technical standards, policies, and implementation specifications.

Minnesota applauds the use of use cases, as the narrative is a powerful way to engage consumers and providers from across the continuum of care. We found the use cases listed were more goal statements. We strongly encourage the ONC to use the User Story Template developed by the Standards and Interoperability Framework, Public Health Reporting Initiative. The following use cases are identified as priorities:

3. The status of transitions of care should be available to sending and receiving providers to enable effective transitions and closure of all referral loops.

5. Population health measurement is supported at the community level and includes data from all relevant sources on each patient in the population and is accessible to providers and other stakeholders focused on improving health.

9. Providers should be alerted or have access to notifications that their attributed patients have had an ER visit, or an admission to or discharge from a hospital.

27. Data for disease surveillance, immunization tracking, and other public health reporting are exchanged automatically.

39. Primary care provider s share a basic set of patient information with specialists during referrals; specialists “close the information loop” by sending updated basic information back to the primary care provider

3. Governance

3.1 The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?

- ONC needs to facilitate discussion on the best process to establish a coordinated governance structure, encourage federal government policy to support and recognize that structure, and align policies and set standards to support nationwide interoperability. This needs to drive us to our outcomes, which may require more prescriptive critical actions.

4. Supportive Business, Cultural, Clinical, and Regulatory Environments

4.1 How can private health plans and purchasers support providers to send, find, or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification? Why or why not?

- Support from health plans and purchasers to send, find or receive common clinical data across the continuum of care is necessary. Many strategies both finical and policy-related need to be implemented. To be supportive health plans and purchasers need to review policies and workflows to identify and eliminate barriers and provide more opportunity for the sending, finding, and receiving common clinical data. Although not related to the common data set, the use of patient generated data can also be supported more by health plans, purchasers, and related entities. For example, the National Committee on Quality Assurance, which accredits health plans, does not allow self-reported data and data from mobile devices. This is a barrier for critical actions in the building block of supportive business, clinical, cultural, and regulatory environments.
- We strongly support private health plans and purchasers to align with federal policies that reinforce adoption of standards and certification. The alignment is necessary for many of the critical actions in Table 2 to be successful and to assure care coordination is provided between private and public health plan beneficiaries.
- In addition, incentives need to extend to providers across the continuum of care and/or to regions that achieve a certain level of interoperability with providers from the continuum of care.
- Support from private health plans and purchasers is necessary for some providers such as dentistry as very little public funds pay for these services, outside of FQHCs and similar organizations.

5. Privacy and Security Protections for Health Information

5.1 What security aspects of RESTful services need to be addressed in a standardized manner?

- This question requires input from the EHR and HIT vendor community.
- There is a strong need to understand what needs to happen and what this means for providers across the continuum of care.

6. Core Technical Standards and Functions

6.1 Which data elements in the proposed common clinical data set list need to be further standardized, and in what way?

- Using the IOM report Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2, Minnesota has looked at the standards used to capture social determinants of health. This work has identified a need for national consensus on most social determinants of health including sex, race, ethnicity, preferred language (written or spoken), and smoking status. This discussion MUST include providers across the continuum of care and have strong consumer engagement.
- Smoking status is too limited. We encourage looking at tobacco use and then other substance use/abuse.
- Some Minnesota providers, EHR and HIT vendors, and other stakeholders support standardizing the public health registries across states to all use the same requirements. This can save costs and resources (to providers and states) while also aligning the data received. CDC should lead this work to develop standards and requirements that meet 80-90% of states' need.
- Mapping interpretation is a barrier to the common clinical data set. Guidance on best practices and/or a minimal set of specific SNOMED codes for the dataset could assure more consistent data results.

- Need more direction from CMS on what exactly constitutes as a procedure. Minnesota providers have found that organizations only map the most “relevant” procedures (procedure activity act for procedures that alter the physical condition of the patient). While other procedures are not mapped. The difference in the number of procedures is in the 10s of thousands.

6.2 Do you believe the proposed approach for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers? Why or why not?

- The approach is not without concerns or barriers to implementation. The ONC needs to thoroughly monitor and evaluate the approach and identify and communicate identified and potential limitations. Ultimately, the ONC must develop or facilitate policy, workflow and technical standardization for matching.

7. Certification and Testing

7.1 In what ways can semantic interoperability be best tested? (e.g., C-CDA content and semantics)

- Minnesota had no comments on this questions

8. Measurement

- For all information on Measurement, please go to comments on Table 15.