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The Office of the National Coordinator for Health Information Technology

Re: Connecting Health and Care for the Nation – A Shared Nationwide Interoperability Roadmap

To Whom It May Concern:

The New York City Department of Health and Mental Hygiene (the "Department") submits the following comments concerning the draft "Connecting Health and Care for the Nation – A Shared Nationwide Interoperability Roadmap" (Version 1.0):

1. General

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?

The actions laid out in the draft interoperability roadmap reflect an ambitious agenda for action. We applaud the roadmap's attention to the needs of multiple stakeholders, both within and outside of the clinical community, and the need for collaborative efforts to overcome barriers to nationwide interoperability. The barriers outlined in the document are reflective of the barriers that we have observed in our work; critical actions (3) and (4) are similarly reflective of our understanding of the highest priorities for action. Regarding critical actions (1) and (2), we concur regarding the overall priority level but caution that efforts to standardize processes and technical standards must be balanced with the need to support and promote free market innovations. We are encouraged to see leveraging market innovation to meet the needs of the evolving health system explicitly called out as a guiding principal and similarly that creating a supporting business, clinical, cultural, and regulatory environment is a core building block of the roadmap. Finally, we identify development of state and local HIE infrastructure as a fifth critical action. We see robust state and local interoperability networks and policies as necessary prerequisites to achieving nationwide interoperability. In New York, strides towards interoperability have been made with regional health information organization participation and the operation of the Statewide Health Information Network of New York (SHIN-NY). Other states have experienced impressive successes in building HIE infrastructure and supporting provider connections, but many will need to make

significant progress in defining and developing infrastructure before they can be full members of a nationwide interoperable HIT ecosystem.

2. What, if any, gaps need to be addressed?

The most significant technological gaps are:

- a. Unstructured data While the need for healthcare providers to be able to write and store clinical notes is recognized, interoperability requires the standardization of key data elements. Clinical notes can be one component of a fully structured message, as long as other required data elements are captured and communicated electronically.
- b. The Direct Project's use of SMTP/E-mail for message delivery The need to support SMTP servers specifically for the Direct project and the ability to manually send unstructured E-mail messages are significant barriers to interoperability that should be phased out over time. The roadmap doesn't specify how SMTP/E-mail will be phased out.
- c. CCD/CDA document implementation Variations in the implementations of the CCDs are also barriers to interoperability. The roadmap has some ideas for reducing the variation, but it doesn't provide a timetable for standardizing these CCDs; it assumes that the documents that were created specifically for RHIOs/HIEs will be replaced by standard messages.
- d. Web-based API The easiest message delivery standard to implement is the one with the smallest number of simple, web-based API functions. Ideally, one API call should suffice for all health message types (including queries); this call can include both message text and binary data (e.g. images) as parameters, has a return value, and can be processed in real-time. The greater the variance of required API calls for interoperability, the more interface software development work has to be performed by transmitters and receivers of health information messages.
- e. Administrative health information Page 18 explicitly excludes administrative electronic health information, but doesn't define it. The exclusion of administrative electronic health information is a significant gap in the interoperability roadmap, especially because it's part of a 10-year plan.
- 3. Is the timing of specific actions appropriate?

Yes, except for the missing target dates for addressing items 1.2.b and 1.2.c above.

4. Are the right actors/stakeholders associated with critical actions?

Yes, except for item 3 (Governance) below.

2. Priority Use Cases

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 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.

The priority use cases listed in Appendix H address numerous aspects of HIE, but are a disparate group that vary in terms of their applicability to the vision laid out in the roadmap. Selecting only three from this list presents the challenge of appropriately representing the scope and utility of a massive project; we instead reviewed the list and identified seven major themes under which the use cases fall. We propose that the ONC consider using the publicly submitted priority use cases to inform the creation of domains under which specific use cases can be prioritized. We have noted with an asterisk the use cases in which we have heard multiple constituents in NYC express specific interest and the use cases which we feel could substantially improve health care delivery. We propose the following domains:

- 1. Care coordination (2, 3, 4, 6, 8*, 9, 11, 26, 29, 30, 33*, 39, 40*, 41, 42*, 43*, 44*, 46, 49, 50*)
 - a. We identified this as the top priority for the development of technical standards, policies and implementation specifications. This is an area of high priority for health care reform and payment reform, and an area in which HIE can substantially improve provider and system capacity to achieve these goals.
- 2. Public Health and Social Support Data Exchange (1, 5, 27, 31, 45, 47*, 51)
 - a. Exchanging data with public health or social support entities, other health registries, and clarifying ability to use HIE for population health tracking or planning (e.g., immunizations, vitals, demographics) is a high priority domain for ensuring that HIE can be used to support health at the population level as well as at the individual level.
- 3. Telehealth (14, 48, 52)
 - a. Telehealth is receiving additional focus as CMS and private payers move to expand coverage; HIE can facilitate the expansion of new mechanisms for care, such as electronic communications and at-home monitoring devices.
- 4. Payment Reform and Cost Management (22, 23, 24, 25, 38*, 53, 54)
 - a. HIE can support payers, providers, and patients in monitoring and understanding documentation, benefit coverage, authorization needs, and quality measurement and facilitate transition to pay-for-value payment structures.
- 5. Access for Individuals (7, 17, 18, 19, 20, 21, 28, 35, 36, 37*, 56)
 - a. Prioritizing the development of standards and tools to enable individuals to access and use HIE promotes patient-centered care and individual capacity to understand and use one's own health data.

- 6. Genomics testing and other diagnostic data, such as images, etc. (12, 13, 34)
 - a. Opportunities to expand HIE to incorporate genomic data for personalized care are comparatively less explored; incorporation of other diagnostic data, e.g. X-rays, will contribute to an expanded understanding of HIE capacity.
- 7. Enrollment in research or other public programs (15, 16, 32, 55)
 - a. Further expanding HIE capacity to support research and assessment of eligibility for public programs through identification of areas, e.g. SSA functional capacity assessment, in which HIE data can create more efficient processes.

3. Governance

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 can support the governance effort by taking the lead, gathering the key players, including EHR vendors, successful RHIOs/HIEs, public health, standards development organizations, clinicians, and driving us all to standardize message content and delivery mechanisms. EHRs, RHIOs/HIEs, doctor's offices, and hospitals are all in competition with each-other. They seek to increase their market share at the expense of their competitors. Standard communication between disparate health information systems isn't in the commercial interest of the most powerful health systems in our economy. Government guidance and leadership continues to be a critical success factor.

4. Supportive Business, Cultural, Clinical and Regulatory environment

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?

We agree with the focus on creating a clear business imperative for interoperability. We strongly agree with the challenges cited in this section. Conflicting market forces drive a fragmented landscape in which interoperability incentives are intermittent at best. The healthcare system as a whole is engaged in a dramatic shift towards pay-for-quality, which will drive one end of the business case for interoperability. However, the technology landscape must evolve to match, creating seamless, useful, and cost-effective tools for HIE. Barriers to interoperability exist on the technology side as well as on the payment side, and costs and utility to primary care providers connecting to HIEs is commonly cited as a major barrier to participation. In a recent poll of primary care providers in New York City, cost was consistently listed as the top barrier to connection. In addition, while NYS HIEs are being subsidized by state funding, HIEs still charge fees for added services and connection fees can vary widely depending on EMR vendor and chosen HIE, creating a lack of clarity around the total one-time and ongoing costs of

participation. We suggest that creating transparency in pricing structures may be a useful tool for providers seeking to understand the costs to participation.

Liability risk is, anecdotally, a frequent area of concern for primary care practices. Two scenarios have been noted as areas of concern: First, is a provider who has access to a HIE containing information on a specific patient but does not use that information in treatment decisions liable if the available information would have made a substantive difference in treatment decisions? Second, if a provider accesses patient information on a HIE that is incorrect (due to being outdated, incorrect entry, etc.), is the provider liable for negative outcomes due to treatment decisions affected by incorrect information? Anecdotally, uncertainty around these and related areas affects provider perception of the value proposition of HIE participation. We ask for guidance and support from the ONC as state legislatures consider the legal ramifications of HIE participation.

We applaud the intent to pursue a cycle of policies that begins with incentives and incorporates mechanisms to promote HIE within delivery system and payment reform.

5. Privacy and Security Protections for Health Information

1. What security aspects of RESTful services need to be address in a standardized manner?

The patchwork of federal and state laws and regulations addressing privacy protections for health information creates a major barrier for individuals and providers striving to ensure that all needed protections are in place while exchanging and using health information. We applaud efforts to streamline the legal and regulatory environment around patient privacy and data protections, and see this as an important avenue to minimize confusion and ensure that providers and patients alike can be confident that they are using HIE in safe and appropriate ways. Alongside patient privacy and data protections, the variation among patient consent requirements is an issue for health information exchange in some states. There is significant variation across states; in New York the proposed regulatory scheme which would govern New York's statewide health information exchange networks, to which most HIEs in New York State will connect, would require that a connected HIE only allow access to patient information by a health care provider with written authorization of the patient or patient's representative. Such variation contributes to the patchwork nature of the national HIE landscape, and may represent an additional area of emphasis for the efforts outlined in the roadmap to reduce variation in the policy environment around privacy and HIE.

We concur that the development of more granular patient choice in terms of specifying which data elements can be shared and which users will have access will promote privacy protections while making it easier for stakeholders to understand the appropriate uses of health data. This is particularly relevant for public health stakeholders for whom health data represents a unique opportunity to understand and act to improve the health status of the community. We request that public health departments be explicitly included among the stakeholders for LHS requirement G.

We also note that the involvement of EHR and other vendors in this process is particularly vital; ensuring that collaboration amongst stakeholders is coordinated such that decisions about the policy and regulatory environment are communicated to vendors in ways that support technological development within the timeframe laid out in the roadmap. The development processes needed to ensure that patient choices, both granular and basic, can be appropriately recorded and handled within the EHR and that EHRs can appropriately communicate that information to HIEs will be complex; inability to segment data within EHRs is often cited as a barrier to information exchange for providers who handle specific types of medical care such as substance abuse treatment.

However, to answer the question posed more specifically, RESTful services are only one form of Web Services. SOAP/XMLP Web Services have mature security solutions. It's unclear why RESTful services are a foregone conclusion, given that SOAP/XMLP services have historically been preferred by EHR vendors, especially those who use Microsoft's .net development environment, due to its built-in support for SOAP Web Services.

We suggest that representatives from public health, EHR vendors, SDOs, and HIEs vote on a standard the type of Web Service (SOAP or REST), and then agree on a standard API that everyone will have to implement, in order for interoperability to succeed.

6. Core Technical Standards and Functions

1. Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?

All elements in the proposed common clinical data set list (and much more) need to be fully standardized into electronic health messages. As mentioned in item 1.2.e, the exclusion of administrative health information is a significant gap, especially in a 10-year plan.

The mention of "immunizations" as a component of the common clinical data set requires a link to the standard public health immunization data set list at:

http://www.cdc.gov/vaccines/programs/iis/func-stds.html#appB

2. Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?

The proposed approach is the starting point that is currently being refined and informed by the ONC Patient Match Community of Practice. This is a work in progress that will take years to mature, but it has the potential to have a positive impact on the community.

7. Certification and Testing

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

Use standard message formats to standardize all lookup code sets and require all electronic data interchange partners to map their internal values to those standard code sets when they communicate health information. Anyone whose messages fail to meet any of those standards fails the test. Everyone whose messages succeed at meeting those standards passed the test.

8. Measurement

1. Does the measurement and evaluation framework cover key areas? What concepts are missing?

The measurement and evaluation framework covers key areas. The concepts are all present; the only thing that's missing is the specific baseline and target measures.

2. Which concepts from the framework are the most important to measure? What types of measures should be included in a "core" measure set?

Query success rate over time, as a percentage is a useful measure. Specific data elements that lead to query success is another useful measure. Reasons for query failure (e.g. duplicate or no record) is another useful measure. The causes of duplicate records (e.g. data quality, matching algorithm, common names, etc) are also useful measures.

3. Should measurement focus on certain use cases, priority populations or at certain levels of the ecosystem (e.g., encounter, patient, provider, organization)?

All levels of the health IT ecosystem that receive financial incentives or federal grants should be measured. Incentives and grants should be focused on a targeted set of specific, attainable use cases, then build on those successes yearly.

4. What other types of metrics have been successfully used at the local or regional level that might be considered for nationwide use? Would stakeholders be willing to propose novel metrics and provide "test beds" to assess the potential for nationwide use?

See question 8.2. Public health would be willing to propose novel metrics and provide existing or novel results to help inform federal policy.

5. What measurement gaps should be prioritized and addressed quickly?

It's difficult to identify the potential gaps at this point.

6. What other available data sources at the national level could be leveraged to monitor progress?

CDC's Immunization Information System Annual Report is a good data source that can be used to monitor progress of immunization data exchange, as can quarterly progress reports from CDC's Interoperability Project Grantees.

7. Are the potential mechanisms for addressing gaps adequate? What are other suggestions?

It's difficult to know if the potential mechanisms are adequate at this point.

8. How should data holders share information to support reporting on nationwide progress?

Data holders who receive incentive payments should be required to produce a standard annual report containing information needed by ONC to measure progress. In addition to the standard report, data holders should continue to share their experiences with other members of the community using national calls, meetings, conferences, and through other less formal means of collaboration.

9. What are appropriate, even if imperfect, sources of data for measuring impact in the short term? In the long term? Is there adequate data presently to start some measurement of impact?

Immunization Information Systems are good sources of data for measuring impact in the short and long-term. New York City has adequate data to measure impact for Meaningful Use Stages 1 and 2, will continue to measure impact if immunizations are included in Stage 3, and is contributing results and information ONC's Patient Matching Community of Practice.

The Department appreciates the opportunity to comment on this important Roadmap. Thank you for your consideration.

Sincerely,

Thomas Merrill General Counsel