April 2, 2015

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Greenway Health Comment
Connecting Health and Care for the Nation:
A Shared Nationwide Interoperability Roadmap

Dr. DeSalvo and staff,

On behalf of more than 70,000 providers nationwide utilizing Greenway Health solutions to coordinate care in ambulatory, enterprise and health system settings, including those serving patients in FQHC and CHC clinics, Greenway welcomes this opportunity to comment on ONC's interoperability roadmap as published January 30, 2015.

Since our inception, Greenway has made data liquidity a key priority within our customer service goals, done through R&D and commercial partnerships, and by taking on collaborative leadership roles within the health information technology marketplace and industry.

Today, through our hub-based exchange technology that eliminates more costly point-to-point implementations, we manage more than 12,000 interfaces and connect with more than 1,000 external vendors as well as multiple state and regional HIEs, combining to produce approximately 12 million messages per month.

Greenway Health has tested onto the national eHealth Exchange, which enables our provider and clinician customers to onboard onto a network that currently includes nearly one-third of all U.S. hospitals and 10,000 medical groups encompassing another 100 million patients. Our ability to conduct cross-vendor exchange reaches beyond ambulatory settings to those of both Epic and Cerner systems, for example.

Like the collaborative approach ONC is putting forth in the roadmap, Greenway is a founding member of both the CommonWell Health Alliance and Car*e*quality, and was the first ambulatory service provider to join Healtheway. We were also the first ambulatory solution to receive IHE-USA interoperability certification.

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Greenway agrees with the overall spirit and intent of the roadmap — that efficient and secure national interoperability is a multi-stakeholder endeavor requiring collaboration around governance, standards, data commonality and scalability.

We also support the roadmap's overall language on examining provider incentives to help achieve interoperability goals, and emphasize that in addition, vendor development costs incurred to meet current and future interoperability standards and implementation should also be examined toward areas of relief. Too often, realistic connection costs incurred by providers — whether within a vendor network, immunization registries or to join a state, regional or national HIE — are pointed to as barriers of interoperability.

And while provider incentives may be one approach, we note that providers are already immersed in various quality reporting programs that include penalties or payment adjustments within prescriptive timelines, similar to what is being articulated in the roadmap concerning future interoperability incentives.

Taking any additional financial or programmatic interoperability requirements off of caregivers and considering ways in which vendors can cost-effectively scale interoperability is equally important. Private payer incentives already underway within PCMH and ACO models create real and useful business cases that can positively impact interoperability acceptance and enthusiasm, as would the continued alignment of federal quality reporting programs.

We also agree with roadmap language concerning patient incentives given by private payers as a factor in advancing aspects of interoperability around provider-patient communication, and related language on payers in effect steering patients to providers using complete or advanced health IT systems.

Patients cannot be left out of the data liquidity equation. We also support related language that caregivers be held to a rational standard of utilizing interoperable health IT solutions to then be considered for inclusion into a private payer network.

Greenway believes that the health IT industry has made great strides in advancing data liquidity within key pillars of the roadmap such as standards, clinical data sets and privacy and security. In addition, health IT industry collaborations are also advancing critical areas such as records location and patient matching.

For the continued advancement of interoperability, Greenway believes that a public-private partnership maintaining a non-regulatory approach by federal agencies and with minimal to no Congressional oversight — unlike recent interoperability draft legislation from the House Energy & Commerce Committee — will encourage existing marketplace collaborations to continue to grow and innovate.

We do, though, see areas in which ONC could and should act as a national facilitator or convener of best practices within key roadmap areas.
As to specific topics of which ONC has asked for reaction, and from elsewhere throughout the roadmap itself, Greenway offers the following detailed comments matched to titled sections and action items.

Learning Health System

Greenway supports the concept of a learning health system as described in the roadmap, one that understands, as stated, that "most determinants of health status are social and are influenced by actions and encounters that occur outside traditional institutional health care delivery settings, such as

employment, retail, education and other settings."

Greenway has established partnerships with the nation's largest retail chain currently offering healthcare in that setting, and with the leading provider of employer-based worksite health clinics. In both settings we provide the EHR and data exchange functionality to advance patient record integration and care coordination across different healthcare IT systems.

We share ONC's enthusiasm for a multi-layered learning health system and emphasize your understanding of it as a long-term approach due to the robust goals of integrating interoperability, clinical research, sophisticated analytics, quality metrics and patient participation into workflows across a patient's care continuum.

We note that crossing this ambitious finish line encompasses the roadmap's overall 10-year scope, and that this process should be closely examined to assure that timelines for this and other aspects of the roadmap often divided into three-year goals, do not constrain the adoption of truly effective care.

In relation to this, Greenway identifies the inclusion of 2015 edition certification standards - as part of the MU3 proposed rule — for the collection of social, psychological and behavioral health data as an alignment approach toward a learning health system. We would just caution — and fully expect — that ONC and CMS pursue all future certification requirements not as a prescriptive means to any individual quality program ends, but as a necessary part of the learning health system and roadmap structure. We would also expect not to see these types of data collection requirements or particular thresholds being differentiated among the range of quality programs or payment models administered by HHS.

Near-Term Wins

As labeled in the roadmap, Greenway Health agrees with the short-term or 'near term wins' priorities of establishing a common clinical data set and clarifying privacy and security requirements that enable interoperability. Privacy and security concerns are a foundation for roadmap success. We have found that many providers are not motivated to share data due to concerns about its security once it leaves that provider's system. Failure to clarify these requirements could inhibit movement in other key areas and trust in the governance framework.

Timelines and Governance

Here too a realistic approach to prioritization is required. As stated in the timeline chart on page 15, the flow of introducing and implementing governance, standards, regulation and the use of technology is overly ambitious.

To set a successful roadmap course, all stakeholders need to collaborate and agree on a set of high-value use cases integrated into the governance structure.

While again we see some alignment between API certification proposed within MU3 and the implementation of the FHIR spec for the common clinical data set plotted for 2016 within the roadmap, it's important to differentiate that FHIR is a standard that must be developed through mutually agreed upon high-value use cases and governance. This and other aspects of 2015 certification to be rolled out for MU3 could create early hurdles or speed bumps to the overall roadmap. Here we also see shortcomings in related FHIR API language in documents such as the Burgess bill. While API specifically has a place in data exchange, the movement cannot succeed without carefully constructed use cases aligned with privacy and security.

These noted aspects coupled with roadmap rollouts of C-CDA2, data provenance and the aforementioned privacy and security requirements all within a two-year window need greater prioritization, again coupled with aligned governance factors, and again based upon the development of high-value use cases.

Greenway Health suggests that the formation of the common clinical data set, privacy and security requirements, a collaboration on high-value use cases and governance pertaining to these aspects is a logical and realistic roadmap start, all while developers must also work toward 2015 certification.

And while Greenway agrees that a holistic and collaborative governance framework is a credible and paramount goal for national interoperability, many factors need to be taken into consideration and whether a segmentation approach is more workable.

Governance needs to encompass the principles, processes and entities of all interoperability stakeholders. Governance needs to consider the clinical, business and administrative perspectives around minimum necessary rules for authentication and provenance, applicable standards which we reiterate should be based on mutually set high-value uses cases, along with content, vocabulary, directories and other considerations.

It is doubtful that one governance body could lend the expertise to cover the depth and breadth of the trust, standards, regulatory and provider and patient entities rightfully identified as the needed integration for this roadmap to succeed.

Added into a segmented or work group, yet comprehensive, governance approach on key areas should be an examination of patient ID and matching. Roadmap language in its final form should address whether — in the continued absence of a national patient identifier — existing matching programs can suffice. And in this area collaboration with private marketplace development of patient identifiers and matching must be considered.

State Roadmaps

While Greenway Health agrees that state-based considerations of an overall national roadmap makes sense, primarily in the area of Medicaid data and quality program integration, we are very concerned about roadmap language that, “roughly half of all states should enact state-autonomous policies to advance interoperability that go beyond their current efforts” by the end of 2017. On its face this language is arguably counter to a streamlined and national interoperability system.

While we presume that this approach is to be integrated into the national roadmap and that development includes the ability for private physicians and payers to exchange data with state systems, Greenway calls for much greater clarity in ONC’s definition of “state-autonomous policies.”

As noted earlier in this comment and as put forth in meetings with ONC, health IT developers are already struggling within the meaningful use program to interface with individual state immunization registries. This adds to the cost structures which again impact developers and providers.

Much more careful language and clarity needs to be brought to this aspect of the roadmap’s call to action section.

Patient Empowerment and Data

In this critically important goal and section of the roadmap, and for a learning healthcare system to be successful, Greenway Health recognizes that patient-generated health data, portals, Blue Button and third-party applications all have merit.

Gauging widespread patient desires can be tricky, beyond how they may respond to surveys showing that more want access to their data and expect data to be interoperable.

Even more hard to gauge is patient behavior. For these aspects of the roadmap to be successful, we again call for front-end, high-value uses cases. Tracking how patients historically use Blue Button data, for example, and enhancing these features can drive more value to the patient. Likewise with third-party applications, which have the potential to become a high-value use case and source of provider-patient data flow, it is important to establish value and usage before building capabilities and deeming that a success for interoperability. Success only comes if patients see value and use the tools before them.

For patient-generated health data, once again we note the alignment with MU3 proposals, but seek definitive clarity on timelines. For it to become a Stage 3 measure requiring more than 15 percent of unique patients to accomplish, patients must see the value, similar to the challenges of meeting MU VDT requirements.

We note the call to action that patients should contribute data beginning in 2018, while some EPs will be prepared to begin Stage 3 in 2017, regardless of the flexibility of the 2018 start date. At the same time and as previously noted, healthcare IT developers are called upon to have 2015 edition rolled out by a 2017 start date. We would also seek clarity that ONC defines patient-generated health data as that being placed directly by the patient, and not via a device?

For active patient engagement to succeed, and within the roadmap's structure of two, three-year time periods and one, four-year period matched with goals and calls to action, Greenway proposes that the time period from 2015 to 2017 be focused on fostering care plans, workflows and processes that patients and providers would mutually benefit from in terms of how data is used and shared. Once these aspects are understood, the realistic need for offering interoperable or functional enhancements can follow suit.

Provider Calls to Action

Addressing arguably the most important factor in the advancement of interoperability, Greenway Health supports the roadmap's inclusion of providers into all levels of governance, and as previously stressed, we suggest providers should also have a key voice in the establishment of high-value use cases that should drive functionality as well as the roadmap's formation of a common clinical data set.

As with patient behavior, examining provider culture, concerns and workflows around data exchange and patient care will gauge the demand and functionality to be met, rather than the other way around.

(Note on workflows: Though we realize that overall, workflows were deemed outside of the scope of this roadmap, workflow considerations should not be wholly excised from the input of providers in terms of governance, use-cases and functionality, particularly in terms of building consensus on functionality and care goals that fit into workflows that can be as universally determined as possible. We would also note that roadmap language does crossover into areas of workflow. For example, roadmap language around single sign-on, which we agree is a credible navigation goal, does speak to workflow.)

To further our comment on providers "embracing a culture of interoperability," specifically as related to workflow, providers should address the amount or types of data to be pushed and pulled, which again should drive functionality.

As to roadmap language on leveraging and measuring data "beyond their internal systems" for population health analytics and quality measures, we agree that clinical data is and should be used for these purposes, but we are not sure that the action of moving that data to prescribed areas is the role of the provider. We seek clarity on the very specific intent of this language, and we call for the continued alignment of quality measures taking place. This intent also speaks to workflows.

Further in line with this call to action, Greenway Health assumes that alignment and the use of healthcare IT solutions will be an integral part of the administration's newly launched Health Care Payment Learning and Action Network, with the goal of advancing new payment models and bundled payments. As the healthcare reimbursement system moves away from fee-for-service medicine, by both private and public payers, and through Congressional efforts such as those around SGR, it is important that quality reporting programs simplify data exchange and reporting. We suggest that the nearly 3,000 organizations already involved in the Network become integrated into roadmap governance and use-case considerations concerning data reporting and payment models.

We believe that overall providers will begin to embrace quality programs if they have voice on programmatic clinical goals, including those "beyond their internal systems."

We also agree with provider calls to action language around utilizing standards-based healthcare IT functionality to prioritize transitions of care, CPOE, electronic prescribing and other well-established functions. Here too the language speaks to workflow, and we believe that the data inherent in these stated functions should be reconciled with the common clinical data set.

In other areas within the provider calls to action section, Greenway supports the call for providers engaged in clinical research to expand collaborations with "research institutions and other public and private stakeholders" to further strategic plans for research-driven healthcare. This has long been a Greenway priority manifested in PCORI registry work with Vanderbilt University and through historic collaborations on clinical trials many of our customer sites have entered into.

For research to advance we would stand fully engaged to aid in this endeavor, and specifically in terms of roadmap language, we would seek clarity on what the interoperability expectations are and would be in this area. We believe this is another area in which the establishment of high-value use cases would benefit the functionality needs that would follow.

As to language calling on providers to support consumers in the downloading or transmitting of health information, we see the parallels with meaningful use VDT measures. Given the so far uneven success and embrace of this process — which we believe has value to all stakeholders — we believe this is an example where use-case scenarios should be examined, in line with our comments on Patient Empowerment and Data.

We close our comments on this section by reiterating that we support the examination of interoperability business case and incentive program options benefiting providers and tied to clinically sound care delivery.

Privacy and Security: Cybersecurity and Encryption

We welcome ONC's comprehensive approach in these areas by combining the expertise and efforts of federal agencies such as OCR, ASPR, ISAC and NIST, and by understanding and constructing language around HIPAA implications.

To expand the stakeholder approach during the stated 2015-2017 timeframe for this collaboration, Greenway urges that expertise from the national Electronic Health Record Association (EHRA) be included at the outset. Greenway Health is a co-founding member of the organization, and through its 2013 Code of Conduct and ongoing privacy and security workgroups, EHRA leadership can impart critical healthcare IT-centric requirements for this process. The organization can also bridge necessary and important training and education in this area to provider and patient levels.

In terms of roadmap language on developing at-rest and/or in-transit data encryption, we believe much of this is addressed in 2014 Edition certification and recommend that a gap analysis approach would be more beneficial and streamlined for all stakeholders.

We do support the examination of security around third-party or healthcare applications impacting mobile devices and EHR integration, as this growing factor — open for more expansion according to MU3 proposed rules — provides only marginal or basic security.

Disclosure and Consent

Overall we support the intent or theory of offering basic and granular choices to patients in regards to the disclosure of their health information that can be captured electronically, but caution that this examination must be sensitive as to whether granular choices would remain clinically relevant to providers.

In staying true to the concept of a learning health system we recommend a careful examination of basic choice content and context which is then used to inform a movement into granular choices.

This approach does apply to the emergence of API data exchange and data granularity, which must match consent management.

Greenway Health supports language in this category pertaining to the 2018-2020 timeframe calling for state governments to align with federal HIPAA standards and that of basic choice. (We also briefly direct our comments back to the State Roadmaps section to again recommend an examination of "autonomous" language in that area.)

Certification and Testing

Greenway supports the collaborative inclusion, as stated, of healthcare IT developers and SDOs being brought into this process. We recommend a gap analysis approach at the outset in regard to certification and a multi-stakeholder review of testing tools.

For developers, certification and testing needs to be a streamlined and cost-effective process that aligns with various roadmap elements around data sets, quality programs, interoperability advances calling for privacy and security review and minimally prescriptive requirements.

We agree that testing throughout the interoperability life cycle is essential. And while overall we do not think that marketplace or industry events like the IHE Connectathon, as it is conducted today, offers the

best scenario for conformance or certification testing, this and other established industry gatherings should be examined as locations that can be expanded to establish and conduct stakeholder collaborations looking ahead to testing procedures, and that this should be pursued and finalized within the first three years of the roadmap timeline.

The merging of healthcare IT developers and SDOs would be for IT stakeholders to develop testing tools while SDOs develop standards and implementation guides collaboratively. We note that efforts where test developers are engaged from the outset of the development of implementation guides have led to more successful and reliable results.

Interoperability lends itself to automated testing tools to ensure the right data is communicated and the respective systems respond appropriately to various error conditions. Connectathons, in their current state, are not a substitute for such testing, but are essential to evaluate standards and implementation guidance definitions before marketplace deployment.

To make use of these established industry gatherings, establishing a process where robust testing tools can validate these operational systems should be examined.

With such tools available, which would be essential to enabling interoperability out of the box, certification should focus on a transparent attestation process on test execution and conformance, as well as monitoring actual implementations to assess areas of improvements through feedback loops merged into the learning health system concept.

Also to successfully make use of Connectathons, the overall scope needs to include both the sender/receiver, requesting/responding parties in the high-value interoperability use case. Only addressing the EHR side of the equation will limit the ability to achieve successful interoperability.

And in keeping with our mission to keep providers and patients first, we suggest an examination of how national provider organizations can test or customize interoperability as we do not believe that providers should only be faced with utilizing the interoperability functions they are given, but should instead have the ability to utilize the types of interoperability that enhance care and workflows while also meeting organizational, reimbursement and population health goals.

Response to specific ONC questions

Greenway Health applauds ONC's inclusion of direct questions to stakeholders and the solicitation of responses, and we have prioritized those in areas not completely covered in the narrative comment.

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.

We agree in general that the more than 50 use cases listed need prioritization, and in line with repeated references in our comment, that prioritization include a set of high-value use cases agreed upon by stakeholders which can realistically drive interoperability functions.

Toward this effort we identify and in several cases group the following from the published list:

- Exchange (query & send) of records core content across organizations (#11, #21, #29,

#33, #46, #47, #49)

- Patient access to an aggregate view of their records (#7, #18, #35)
- Across organization for results sharing (#12, #41)
- Closed loop referrals (#3, #39)
- Alerts to Ambulatory that patient has been hospitalized (#9, #40)
- EHR to Public Health (#1, #27)
- Order submission (e.g., Lab, Imaging) and follow-up cross-organization (#6)

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

To begin a roadmap toward a learning health system, we believe that the clinical relevance of the data elements is as critical as standardization, and for this multi-stakeholder process to succeed, Greenway suggests that a final collaboration be initially constructed on the elements of the common clinical data set, followed by an evaluation of each element as to a further level of standardization.

With its mix of simple and complex data types, we believe the proposed common clinical data set is relevant overall in vocabulary and structure to apply it to use cases and examine static exchange as well as workflow management. Depending on the use case, a push, pull, or combination is most appropriate to yield the most value. Transport methods and APIs may range from Direct to messaging to service-based APIs.

Considering that neither vocabulary nor structure are fully defined or harmonized, we believe that further standardization is necessary in all areas. There are varying perspectives on what the appropriate data set is to capture smoking status, for example. There is also debate on how to express allergies or the absence of allergies. Immunizations can be communicated using a variety of standards and interpretations. Overall we believe we are all better served to approach the data set holistically prior to selecting it or any subset for standardization.

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

Here Greenway Health believes ONC should leverage strides being made in the private marketplace in lieu of focusing on or evaluating one approach, though we certainly believe the approach being questioned has value.

We also believe this process will continue to be a challenge without a national unique patient identifier system, and while we realize the historical and political hurdles this must cross, we continue to urge continued effort within the timelines of this roadmap.

Doing so could reduce ambiguity that the proposed fields raise. For example, how many historical phone numbers and addresses should one be able to maintain and communicate? Should these be send along on every transaction and be part of every discharge summary or other document type? Inclusion of these elements increase the requirements on administrative processes and staff to improve their accuracy to collect and maintain more data used in matching while collecting and maintaining the current set is already a challenge.

For example, we can envision how the proposed AIDM could improve on the ability to match patient data, but the lack of even a partial unique patient identifier to increase matching probability and quality can be equally apparent.

Technology can contribute to standardization, but not to the accuracy of text fields. We are aware of studies that demonstrated that partial SSNs aided in the success of patient matching, and believe that a multi-stakeholder approach would yield a similar consensus.

In Conclusion

In conclusion, Greenway Health supports the spirit and intent of the roadmap, and we believe that through the generalized timelines and abundance of stakeholders included, any real or perceived barriers to seamless and scalable national interoperability can be solved.

We believe the healthcare IT industry and other elements of the private marketplace have made great strides in interoperability and that today millions of patient records are liquid between many disparate systems and healthcare settings, and that the real challenge is to build upon this success and not reinvent it.

It is a challenging but proper time for ONC and the health IT industry to look beyond external pressures and lend each other the expertise to construct a truly sustainable and coordinated healthcare delivery system.

Please call upon us to aid in this mission, and we look forward to informing future iterations of the roadmap.

Sincerely,

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