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

DRAFT Version 1.0
Executive Summary

Introduction

Health information technology (health IT) that facilitates the secure, efficient and effective sharing and use of electronic health information when and where it is needed is an important contributor to improving health outcomes, improving health care quality and lowering health care costs – the three overarching aims that the U.S. is striving to achieve. Health IT can help health care providers recommend treatments that are better tailored to an individual’s preferences, genetics and concurrent treatments; it can help individuals make better treatment decisions and health-impacting decisions outside of the care delivery system; and can help reduce care delivery redundancy and cost by allowing test results to be reused while supporting analyses to pinpoint waste. To achieve this, however, the health IT community must expand its focus beyond institutional care delivery and health care providers, to a broad view of person-centered health. This shift is critical for at least two reasons:

1. Health care is being transformed to deliver care and services in a person-centered manner and is increasingly provided through community and home-based services that are less costly and more convenient for individuals and caregivers; and
2. 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 in employment, retail, education and other settings.

This shift requires a high degree of information sharing between individuals, providers and organizations and therefore a high degree of interoperability between many different types of health IT, such that systems can exchange and use electronic health information without special effort on the part of the user. The goal of this shift is to a nationwide learning health system—an environment that links the care delivery system with communities and societal supports in "closed loops" of electronic health information flow, at many different levels, to enable continuous learning and improved health. This kind of system allows individuals to select platforms and apps to share and use their own electronic health information to meet their needs without undue constraints.

This shared nationwide interoperability Roadmap describes the actions and roles of a variety of health IT stakeholders needed to achieve the vision described in ONC’s 10-Year Interoperability Concept Paper. This 10-year Roadmap describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system and a suggested path for moving from the current state to the desired future state. The Roadmap lays out a path to achieving the vision in the three-, six- and ten-year time frames and a vision to catalyze

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3 Derived from the Institute of Electrical and Electronics Engineers (IEEE) definition of interoperability.
collaboration and action across government, communities and the private sector. As such, the Roadmap will enable stakeholders to make key commitments and take actions that align with other stakeholder actions, in order for the nation to collectively move towards a learning health system.

**Principle-Based Interoperability: Working Toward a Long-Term Vision with Near-Term Wins**

An interoperable health IT ecosystem that is person-centered makes the right electronic health information available to the right people at the right time across products and organizations, in a way that can be relied upon and meaningfully used by recipients. This ecosystem should adhere to the following interoperability guiding principles (Figure 1).

*Figure 1: Principles of Interoperability*

Based on these principles, this *Shared Nationwide Interoperability Roadmap* identifies functional and business requirements for interoperability and lays out a foundational set of short-term and long-term critical actions for all stakeholders to work towards over the next 10 years in support of a learning health system. This vision significantly expands the types of information, information sources and information users well beyond clinical information derived from electronic health records (EHRs).
Specifically, the Roadmap focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. Although this near-term target focuses on individuals and care providers, interoperability of this core set of electronic health information will also be useful to community-based services, social services, public health and the research community. This includes standardized data elements, such as demographics, that will enable better matching and linking of electronic health information across all systems and platforms.

These standardized data elements support better stratification of electronic health information when aggregated to identify and address important issues such as health disparities and also support research and evidence-based personalized medicine. The intersection of clinical and administrative electronic health information is a critical consideration, but is out of scope for the Roadmap at this particular time. Use cases, standards, technologies and tools that leverage both administrative and clinical electronic health information will be an important topic to address in future iterations. There are also many aspects of health IT beyond interoperability that are important and will be critical to a learning health system, including technology adoption, data quality, usability and workflow. However, these topics are out of scope for this Roadmap at this particular time and deserve separate, dedicated attention.

Given the increasing volume of mobile technology usage among consumers and across the care delivery system, approaches to enable "send, receive, find and use" in the near-term must support the flow of electronic health information across both institutional and mobile-based technologies. This means traditional approaches to health IT interoperability will need to become more agile and leverage the experience of modular consumer applications, such as those created by Facebook, Amazon and Apple. These secure, but simple architectures have enabled an ecosystem of applications that allow users to engage with electronic health information across a variety of different platforms and devices and open opportunities for entrepreneurial third parties to thrive.

**Current Context**

Many successful electronic health information-sharing arrangements currently exist in communities across the nation. These arrangements have often formed around specific geographies, networks and/or technology developers. However, several barriers continue to inhibit nationwide interoperability despite these arrangements and must be overcome rapidly to achieve a learning health system. These barriers include:

1. Electronic health information is not sufficiently structured or standardized and as a result is not fully computable when it is accessed or received. That is, a receiver’s system cannot entirely process, parse and/or present data for the user in meaningful and useable ways. It is also difficult for users to know the origin (provenance) of electronic health information received from external sources. Workflow difficulties also exist in automating the presentation of

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5 Federal Health IT Strategic Plan 2015-2020 Goal One.
externally derived electronic health information in meaningful and appropriately non-disruptive ways.

2. Even when technology allows electronic health information to be shared across geographic, organizational and health IT developer boundaries, a lack of financial motives, misinterpretation of existing laws governing health information sharing and differences in relevant statutes, regulations and organizational policies often inhibit electronic health information sharing.

3. While existing electronic health information sharing arrangements and networks often enable interoperability across a select set of participants, there is no reliable and systematic method to establish and scale trust across disparate networks nationwide according to individual preferences.

A variety of electronic health information sharing arrangements and networks will continue to exist for the foreseeable future, as these arrangements serve important market and clinical functions by meeting the unique needs of many different communities. In a country as large and heterogeneous as the U.S., it is not realistic to suggest that all health information needs will be met with a single electronic health information sharing approach. However, the health IT ecosystem must evolve to address each of these barriers in a lasting and meaningful way to achieve a learning health system that protects the health of all Americans and provides essential human services to all.

While each electronic health information sharing arrangement may continue to use its own policies, service agreements and technical standards to support participant priorities and needs, a common set of policies and technical standards must be adopted across the ecosystem to support nationwide interoperability and transcend these disparate networks. This will provide electronic health information users the flexibility to use services with deep local electronic health information sharing functions that meet many of their day-to-day needs, while having the confidence that they can still engage in key universal transactions with any authorized users in any network.

This approach is consistent with the way the Internet operates today and with the interoperability trajectory experienced in other industries, such as telephone and ATM networks. Such market-based network development is critical to the achievement of nationwide interoperability. HHS will consider where additional guidance may be needed to clarify the current legal framework, including Health Insurance Portability and Accountability Act (HIPAA) Rules, to effectively support individual privacy in a learning health system.

**Critical Actions for Near Term Wins**

The four most important actions for public and private sector stakeholders to take to enable nationwide interoperability of electronic health information through health IT in the near term are: (1) establish a coordinated governance framework and process for nationwide health IT interoperability; (2) improve technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhance incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarify privacy and security requirements that enable interoperability. Additional actions are needed in several other areas such as clinical culture, state and
organization-level policies; these actions are described in greater detail throughout the Roadmap. However, these four foundational actions are linchpins to achieving the near-term and long-term goals described in Connecting Health and Care for the Nation (Figure 2). Below are more detailed near-term actions for each of these high priority areas.

1. **Establish a coordinated governance framework and process for nationwide health information interoperability.** As described above, the proliferation of health information sharing arrangements has created many different processes and rules for interoperability among sub-components of the health IT ecosystem. To enable nationwide interoperability for a common clinical data set, there must be agreement on the policies, operations and technical standards that will enable trust and allow information to be shared appropriately across the ecosystem. To that end, ONC will ensure the establishment of (1) a governance framework with overarching rules of the road for interoperability of health IT, (2) a public/private process for addressing implementation or operational-level issues and (3) a method for recognizing the organizations that comply with the rules and hold them accountable for continuing to do so. Public and private stakeholders will need to come together through a coordinated governance process to establish more detailed policies regarding business practices (including policies for identifying and addressing bad actors) and to identify the technical standards that will enable interoperability for specific use cases. See the Governance functional requirement for more detail on coordinated governance.

2. **Improve technical standards and implementation guidance for sharing and using a common clinical data set.** This basic set of electronic health information must be accessible via clinical documents (for example, in a care summary) and as discrete data elements (for example to plot blood pressure over time). It is unlikely that the care delivery system will stop using clinical documents for specific purposes in the near term (or perhaps the long term) and mobile technologies and applications will need to simultaneously access specific data elements to support individuals in the near term. The purpose for which electronic health information is shared and used must drive the technical standards and methods selected for nationwide adoption through a coordinated governance process. While coordinated governance processes are established, public and private stakeholders should advance standards that are scalable, high performing and

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### A Common Clinical Data Set

- Patient name
- Sex
- Date of birth
- Race
- Ethnicity
- Preferred language
- Smoking status
- Problems
- Medications
- Medication allergies
- Laboratory test(s)
- Laboratory value(s)/result(s)
- Vital signs
- Care plan field(s), including goals and instructions
- Procedures
- Care team members
- Immunizations
- Unique device identifier(s) for a patient’s implantable device(s)
- Notes/narrative
simple. These standards should enable sharing a common clinical data set, further constrain implementations of the C-CDA and define standards for data provenance at the document and data element levels and implement standards in a manner that makes sharing and receiving electronic health information easy for users. See the Core Technical Standards and Functions building block for more detail on technical standards actions.

3. **Advance incentives for sharing health information according to common technical standards, starting with a common clinical data set.** While the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) have been a primary motivator for the adoption and use of health IT, these programs alone are insufficient to create economic incentives that lead to interoperability across the care continuum and, over time, a learning health system. Experience has demonstrated that current fee-for-service payment policies often deter the exchange of electronic health information, even when it is technically feasible. To ensure that individuals and providers can send, receive, find and use a common clinical data set, federal, state and commercial payers will need to evolve policy and funding levers. These levers should incentivize information sharing according to technical standards designated through ONC’s HIT Certification Program in the near term and standards identified through the coordinated governance process over the longer term. See the Supportive Business and Regulatory Environment that Encourages Interoperability requirement for more detail on payment policy actions.

4. **Clarify privacy and security requirements that enable interoperability.** While health IT developers can design health IT tools that support electronic health information sharing, it is important to remember that the majority of clinical information resides within and is stewarded by health care organizations. Many of these health care organizations are “covered entities” (CEs) and are governed by the HIPAA Privacy and Security Rules. In addition, “business associates” (BAs) must follow parts of the HIPAA Privacy Rule and all of the requirements in the HIPAA Security Rule. Generally, BAs are organizations that perform certain functions or services to CEs that involve the use or disclosure of individually identifiable health information. The HIPAA Privacy Rule was designed to ensure that individuals’ health information is protected while allowing the flow of health information needed to provide high quality health care. The HIPAA Security Rule was designed to protect the privacy of individuals’ electronic health information while allowing the adoption of new technologies that will improve the quality and efficiency of patient care. Therefore, it is important for CEs and BAs to have consistent understanding of these requirements aligned with guidance provided by the HHS Office for Civil Rights.

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6 Vitals in particular should be expanded to include – patient’s body height, body weight measured, diastolic and systolic blood pressure, heart rate, respiratory rate, body temperature, oxygen saturation in arterial blood by pulse oximetry, body mass index (ratio). Vitals should also include date and time of vital sign measurement or end time of vital sign measurement and the measuring- or authoring-type source of the vital sign measurement.
Many organizations have misinterpreted HIPAA rules and other regulations and therefore refrain from sharing health information, even with individuals themselves. Effectively honoring the privacy and security of identifiable health information means that CEs and BAs will never be able to “open” or release identifiable health information writ large to whomever wishes to access it; however, in order to achieve nationwide interoperability, all organizations regulated by HIPAA must understand in the same way that HIPAA, through its permitted uses and its privacy protections, actually enables interoperability. With improved understanding, CEs and BAs will be able to exchange appropriately with greater confidence. This includes ensuring that individuals can exercise their legal right under HIPAA rules to access their own health information. Federal agencies and other stakeholders should work to provide the Office for Civil Rights, which enforces and issues guidance on the HIPAA Rules, with information it needs to determine whether additional guidance is needed to support interoperability while maintaining the crucial privacy protections on which interoperability relies. See the Privacy and Security Protections for Health Information building block for more detail on privacy and security actions.

See Figure 2 for a timeline of select high-level critical actions. These and other critical actions are described in detail throughout the Roadmap. The Roadmap is organized according to the following five fundamental building blocks.

- Core technical standards and functions
- Certification and testing to support adoption and optimization of health IT products and services
- Privacy and security protections for health information
- Supportive business, clinical, cultural and regulatory environments
- Rules of engagement and governance

Within each building block, the roadmap describes functional and business requirements for a learning health system and the associated actions for making rapid near term progress.
Figure 2: Timeline of Select High-Level Critical Actions for Near-Term Wins

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<td>Existing communities agree on coordinated governance process</td>
<td>Coordinated governance process and single trust framework implemented</td>
<td>Coordinated governance process expands and maintains the common rules of the road</td>
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<td>Common rules of the road established</td>
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<td>ONC to publish and annually update a list of the best available standards for interoperability</td>
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<td>FHIR specs for querying a common clinical data set refined and piloted</td>
<td>Tech developers implement/FHIR spec for a common clinical data set</td>
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<td>Data provenance specs published</td>
<td>Tech developers implement spec to support data provenance industry needs</td>
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<td>C-CDA 2.0 released to public</td>
<td>Tech developers implement C-CDA implementation guidance</td>
<td>Tech developers roll out 2015 certified products</td>
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<td>Clarify privacy and security requirements to enable interoperability</td>
<td>All public and private payers to evolve policy and funding levers</td>
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<td>✔ 2015 ed. ONC Cert. &amp; MU stage 3 MPRs</td>
<td>✔ 2015 ed. ONC Cert. &amp; MU stage 3 EHRs</td>
<td>✔ MU stage 3 begins</td>
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<td>Care providers across the continuum use 2014/2014 R2 certified products/services</td>
<td>Care providers across the continuum upgrade to 2015 certified products/services</td>
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<td>Consumers use online portals to access health info</td>
<td>Consumers aggregate health info from many portals in one place via apps</td>
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Disclaimer: Timeframes noted are approximate estimates.