The Foundational Element of Better Health for Everyone in America

Michael J. McCoy, MD, FACOG

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Why?

To enable a health system that provides better care, spends dollars more wisely, and has healthier people

Reward outcomes, not effort
Improving Health

- Improving the health of a nation’s citizens requires health IT that is data driven, interoperable, and provides person-centered quality care.

- To do so, we must ensure that an interoperable health IT ecosystem makes the right electronic health information available to the right people at the right time.

- Sharing information more broadly to providers, consumers, and others to support better decisions while maintaining privacy, is one way of achieving better care, smarter spending and a healthier nation.
Health IT and Delivery System Reform Goals

- ONC focus is on person-centered health IT system that enables open flow of health data across the care continuum

- ONC actions:
  - The Federal Health IT Strategic Plan
  - The 2015 Edition Certified EHR Technology Final Rule
  - The ONC Interoperability Road Map

- To achieve open, connected care for our communities, our **private sector partners must lead** the transformation
ONC’s History

2004
Executive Order establishes the Office of the National Coordinator for Health IT

2005
Initial funding provided to initiate certification of health IT

2009
ONC authority expands under the Health Information Technology for Economic and Clinical Health Act (HITECH)

2010
2011 Edition rule is released – the first regulation governing the certification of Health IT

2012
2014 Edition rule is released - updates the prior certification rule and focuses on health information exchange

2014
Release 2 of the 2014 Edition rule is released – updates the 2014 Edition rule and provides updates based on innovation that has occurred since 2012

2015
National Health IT Strategic Roadmap released
2015 Edition rule is released – updates prior rules based on innovation Interoperability Standards Guide released
Vision

High-quality care, lower costs, healthy population and engaged people

Mission

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.
Federal Health IT Strategic Plan

Goal 1
Advance Person-Centered and Self-Managed Health

Goal 2
Transform Health Care Delivery and Community Health

Goal 3
Foster Research, Scientific Knowledge, and Innovation

Goal 4
Enhance Nation’s Health IT Infrastructure
Federal Health IT Strategic Plan

**VISION**
High-quality care, lower costs, healthy population, and engaged people

**MISSION**
Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most

- **Goal 1** Advance Person-Centered Health and Self-Management
- **Goal 2** Transform Health Care Delivery and Community Health
- **Goal 3** Foster Research, Scientific Knowledge, and Innovation
- **Goal 4** Enhance Nation’s Health IT Infrastructure

**Goal 4**
Objective A: Implement the *Shared Nationwide Interoperability Roadmap*
Learning Health System
A Shared Nationwide Interoperability Roadmap – Final version 1.0

- Priority Data Domains
- The 2015 Edition Certification Rule is referenced in several places specifically:
  - H. Consistent Data Semantics
  - I. Consistent Data Formats
  - K. Consistent, Secure Transport Techniques
IEEE Definition:

- The ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user.

What this should look like:

- All individuals, their families and health care providers should be able to send, receive, find and use electronic health information in a manner that is appropriate, secure, timely and reliable to support the health and wellness of individuals through informed, shared decision-making.
Some history on our progress:

**2011**
- Federal Health Information Technology Strategic Plan 2011-2015
- Meaningful Use Stage 1 begins
- 27% of hospitals and 34% of providers adopted EHRs
- Blue Button Initiative Pledges from the Private Sector begin 2012

**2012**
- The Consolidated Clinical Document Architecture (CDA), a unified standard for summary care records is created
- Healtheway is launched
One-quarter of hospitals nationwide are finding, sending, receiving **AND** using data electronically.

**Find**

- Percent of Hospitals: 48%

**Send**

- Percent of Hospitals: 78%

**Receive**

- Percent of Hospitals: 56%

**Use**

- Percent of Hospitals: 40%

**Conduct All 4 Interoperable Exchange Activities**

- Percent of Hospitals: 23%

**Health Info from outside sources**

**Patient Summary Care Record**

**SOURCE:** ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement

**NOTES:** “Find” is only interoperable exchange activity not specific to summary of care records. Find refers to query. “Send” and “Receive” include routine exchange using secure messaging using an EHR, using a provider portal, OR via health information exchange organization or other third party. “Use” requires that the records are integrated into the hospital’s EHR system without the need for manual entry.
Exchange with outside ambulatory care providers and outside hospitals increasing

Source: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement.

Notes: Percent of non-federal acute care hospitals that electronically exchanged laboratory results, radiology reports, clinical care summaries, or medication lists with ambulatory care providers or hospitals outside their organization: 2008-2014.

*Significantly different from previous year (p < 0.05).
10-Year Overarching Goals and Objectives for Expanding Interoperable Health IT Infrastructure

3 Year Agenda (2015-2017)
Send, receive, find and use a common clinical data set to improve health and health care quality

6 Year Agenda (2018-2020)
Expand interoperable health IT and users to improve health and lower cost

10 Year Agenda (2021-2024)
Achieve a nationwide learning health system
A Health IT Module will need to meet applicable privacy and security certification criteria, which is based on the other capabilities included in the Health IT Module.

Removes the responsibility from the provider to ensure that they possess technology certified to all the necessary privacy and security criteria.
If the Health IT Module includes capabilities for certification listed under:

<table>
<thead>
<tr>
<th>Approach 1</th>
<th>Approach 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>§ 170.315(a)</td>
<td></td>
</tr>
<tr>
<td>§ 170.315(d)(1) (authentication, access control, and authorization),</td>
<td></td>
</tr>
<tr>
<td>(d)(2) (auditable events and tamper resistance),</td>
<td></td>
</tr>
<tr>
<td>(d)(3) (audit reports),</td>
<td></td>
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<tr>
<td>(d)(4) (amendments),</td>
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<tr>
<td>(d)(5) (automatic log-off),</td>
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<tr>
<td>(d)(6) (emergency access),</td>
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<tr>
<td>(d)(7) (end-user device encryption)</td>
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<tr>
<td>§ 170.315(b)</td>
<td></td>
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<tr>
<td>§ 170.315(d)(1) through (d)(3) and (d)(5) through (d)(8) (integrity)</td>
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<tr>
<td>§ 170.315(c)</td>
<td></td>
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<tr>
<td>§ 170.315(d)(1) through (d)(3) and (d)(5)*</td>
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<tr>
<td>§ 170.315(e)(1)</td>
<td></td>
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<tr>
<td>§ 170.315(d)(1) through (d)(3), (d)(5), (d)(7), and (d)(9)(trusted connection)*</td>
<td></td>
</tr>
<tr>
<td>§ 170.315(e)(2) and (3)</td>
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<tr>
<td>§ 170.315(d)(1) through (d)(3), (d)(5), and (d)(9)*</td>
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<tr>
<td>§ 170.315(f)</td>
<td></td>
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<tr>
<td>§ 170.315(d)(1) through (d)(3) and (d)(7)</td>
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<tr>
<td>§ 170.315(g)(7), (8) and (9)*</td>
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<tr>
<td>§ 170.315(d)(1) and (d)(9); and (d)(2) or (d)(10) (auditing actions on health information)*</td>
<td></td>
</tr>
<tr>
<td>§ 170.315(h)</td>
<td></td>
</tr>
<tr>
<td>§ 170.315(d)(1) through (d)(3)</td>
<td></td>
</tr>
</tbody>
</table>

*Emphasis added to identify additions to the framework as compared to the Proposed Rule.
Common Clinical Data Domains

• Renamed from “Common MU Data Set” to emphasize additional use.
• Includes key health data that should be accessible and available for exchange.
• Data must conform with specified vocabulary standards and code sets, as applicable.

<table>
<thead>
<tr>
<th>Patient name</th>
<th>Lab tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Lab values/results</td>
</tr>
<tr>
<td>Date of birth</td>
<td>Vital signs (changed from proposed rule)</td>
</tr>
<tr>
<td>Race</td>
<td>Procedures</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Care team members</td>
</tr>
<tr>
<td>Preferred language</td>
<td>Immunizations</td>
</tr>
<tr>
<td>Problems</td>
<td>Unique device identifiers for implantable devices</td>
</tr>
<tr>
<td>Smoking Status</td>
<td>Assessment and plan of treatment</td>
</tr>
<tr>
<td>Medications</td>
<td>Goals</td>
</tr>
<tr>
<td>Medication allergies</td>
<td>Health concerns</td>
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</tbody>
</table>

ONC Interoperability Roadmap Goal

2015-2017
Send, receive, find and use priority data domains to improve health and health quality

Red = New data added to data set (+ standards for immunizations)
Blue = Only new standards for data
Stakeholder Interoperability Commitments

Three interoperability commitments and specific action asks:

- **Consumer Access**: help consumers easily and securely access their electronic health information, direct it to any desired location
  - Enable open and public APIs

- **Transparency**: help providers share individuals’ health information and not block sharing
  - Implement ONC’s Developer Transparency Attestation, remove artificial barriers

- **Standards**: Implement federally recognized national interoperability standards, policies, guidance and practices, and adopt best practices including for privacy and security
  - Commit to pilot testing and use of ONC’s Interoperability Standards Advisory
ONC accepted public comments on a *draft 2016 Interoperability Standards Advisory* for 45 days, ending Friday, November 6, 2015.

The *Final 2016 Advisory* represents feedback received from public comment on the *2015 Interoperability Standards Advisory*, as well as many of the recommendations from the *HIT Standards Committee*. 
Interoperability Standards Advisory

- **Scope** = clinical health IT interoperability
- **Non-regulatory, straight-forward approach with interactive, predictable process for updates**
- **Reflects “best available” standards and implementation specifications as of end of the calendar year**
- **Designed to create common ground**
  - To provide a single, public list of standards and implementation specifications
  - To reflect results of on-going dialogue, debate, and consensus
  - To document known limitations, preconditions, and dependencies among referenced standards and implementation specifications

- **Overall Goal**
  - A widely vetted resource – in one place, done right (before/without regulation)
  - Enable a “look first” philosophy for government programs, procurements, testing or certification programs, standards development, etc.
### Adoption Level, Maturity, Alternatives

<table>
<thead>
<tr>
<th>Type</th>
<th>Standard/Implementation Specification</th>
<th>Standards Process Maturity</th>
<th>Implementation Maturity</th>
<th>Adoption Level</th>
<th>Federally Required</th>
<th>Cost</th>
<th>Test Tool Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2 - Implementation Specification</td>
<td>IG for Delivery Notification in Direct</td>
<td>Final</td>
<td>Production</td>
<td>⬤⬤⬤⬤⬤</td>
<td>Yes</td>
<td>Free</td>
<td>Yes</td>
</tr>
<tr>
<td>1, 2, 3 - Implementation Specification</td>
<td>XDR and XDM for Direct Messaging Specification</td>
<td>Final</td>
<td>Production</td>
<td>⬤⬤⬤⬤⬤</td>
<td>Yes</td>
<td>Free</td>
<td>Yes</td>
</tr>
<tr>
<td>3 – Standard</td>
<td>IHE-XDR (Cross-Enterprise Document Reliable Interchange)</td>
<td>Final</td>
<td>Production</td>
<td>⬤⬤⬤⬤⬤</td>
<td>Yes</td>
<td>Free</td>
<td>Yes</td>
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<tr>
<td>4 - Emerging Alternative Standard</td>
<td>Fast Healthcare Interoperability Resources (FHIR) DSTU 2</td>
<td>Balloted Draft</td>
<td>Pilot</td>
<td>⬤⬤⬤⬤⬤</td>
<td>No</td>
<td>Free</td>
<td>No</td>
</tr>
<tr>
<td>3, 4 – Emerging Alternative Implementation Specification</td>
<td>IHE-MHD (Mobile Access to Health Documents)</td>
<td>Balloted Draft</td>
<td>Pilot</td>
<td>⬤⬤⬤⬤⬤</td>
<td>No</td>
<td>Free</td>
<td>No</td>
</tr>
</tbody>
</table>

#### Limitations, Dependencies, and Preconditions for Consideration:

- “Direct” standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (MIME) Version 3.2 Message Specification, RFC 5751.
- For Direct, interoperability may be dependent on the establishment of “trust” between two parties and may vary based on the trust community(ies) to which parties belong.
- The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the “RESTful FHIR API”.
- The MHD supplement is based on FHIR DSTU1.1. The IHE MHD committee is currently working to update the MHD profile and planning to release it in the first quarter calendar year 2016.

#### Applicable Security Patterns for Consideration:

- **System Authentication** - The information and process necessary to authenticate the systems involved
- **Recipient Encryption** - the message and health information are encrypted for the intended user
- **Sender Signature** — details that are necessary to identify of the individual sending the message
- **Secure Communication** — create a secure channel for client-to- serve and server-to-server communication
- **Secure Message Router** — securely route and enforce policy on inbound and outbound messages without interruption of delivery.
Interoperability:

The Foundational Element of Better Health for Everyone in America

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