AGENDA

10:00 – 10:15 am  Call to Order and Introductions – Hon Pak, Chair, PEHRC

10:15-11:15 am  Physician Burnout: Impact of Clinical Documentation

- Helen Burstin, MD, MPH, Executive Vice President and CEO, Council of Medical Specialty Societies (CMSS)
- Geoff Caplea, MD, MBA, Medical Director - Regulatory Affairs, Quality Assurance, & Patient Safety, Allscripts
- Corinne Boudreau, Senior Solutions Manager for Physician Experience, MEDITECH
- Marc Overhage, MD, Chief Medical Informatics Officer, Cerner

This session will highlight the recent National Academy of Medicine report and recommendations related to clinical documentation and reduce physician burnout. The discussion will highlight opportunities for physician and society input into efforts to reduce documentation burden.

11:15-12:15 pm  An Update on Direct Interoperability and DirectTrust’s Role

David Kibbe, MD MBA, President and CEO, DirectTrust

This talk will be an interactive discussion bringing the audience up-to-date on the growth and utility of the Direct “push” exchange network and the role of the DirectTrust trust framework.

12:30 – 2:00pm  Join HX360 Executive Luncheon in La Tour Ballroom *(No Dial-in)*

Leading Healthcare Transformation with Innovation, Advanced Analytics, and Technology

Change is the new global reality, especially in healthcare where consolidation, policy changes, and reimbursement instability create more uncertainty. Join our panel of healthcare disrupters for a lively exchange of ideas around the key drivers of the transformation, what should drive innovation, and the role that advanced information/analytics and digital health should play in creating the future.

Speakers:
- Facilitator: John Nosta, President, NOSTALABS & Forbes Contributor
- Barclay Berdan, CEO, Texas Health Resources
- Emma Cartmell, CEO, Cartmell Venture Capital
- Bruce Greenstein, HHS, CTO
- Mitch Morris, Executive Vice President, OptumInsight
- Kathy Powell, CEO, Petaluma Community Health Center

2:15 – 3:00 pm  AMA Integrated Health Model Initiative™: Unleashing a New Era of Better More Effective Patient Care

Laurie McGraw, Senior Vice President, Health Solutions, AMA

In 2017, the American Medical Association launched the Integrated Health Model Initiative™ (IHMI), a collaborative effort across health care and technology stakeholders. IHMI supports a continuous learning environment to enable interoperable technology solutions and care models that will evolve with real-world use and feedback. IHMI uses the best available science to incorporate essential data elements around function, state and patient goals. IHMI includes: (1) digital communities around costly and burdensome clinical areas, (2) a physician-led validation process to review clinical applicability and (3) a data model for organizing and exchanging information. Since the launch in October, individuals from 47 states and 33 countries are on the IHMI platform, and 17 collaborating organizations and over 1,000 participants have joined the initiative.
2:15 – 3:00 pm  AMA Integrated Health Model Initiative™: Unleashing a New Era of Better More Effective Patient Care

Join Laurie McGraw, AMA Senior Vice President of Health Solutions, who will provide an overview of this important effort and learn how you can actively participate in this data evolution for improving, organizing and sharing health care information. [www.ama-ihmi.org](http://www.ama-ihmi.org)

3:00 – 4:00 pm  Trusted Exchange Framework and Common Agreement (TEFCA) Overview
Genevieve Morris, Principal Deputy National Coordinator for Health Information Technology, ONC

Learn more about the Trusted Exchange Framework and Common Agreement (TEFCA) and have your questions answered.

Optional Events for In-Person Attendees
4:00 – 5:00 pm  HIMSS18 CMIO Roundtable
Venetian Convention Center | Galileo 904

4:45pm - 5:15pm  Investing in a Better Future for Medicine with Connected Care
Bellini 2105/2106, Level 2, The Venetian

5:00 – 6:00 pm  HIMSS18 CMIO Roundtable Reception
Venetian Convention Center | Galileo 904

5:30 – 7:00 pm  HX360 Executive Reception
Wynn Tableau
PEHRC members welcome to join

[Additional physician focused education and networking at HIMSS18](http://www.HX360.com)
An Overview of Direct Exchange and DirectTrust, and A Very Brief Intro to the 21st Century Cures Act HIT Provisions

David C. Kibbe, MD MBA
President and CEO, DirectTrust

March 2018
• Founder, President, and Chief Executive Officer of DirectTrust
• Dr. Kibbe serves as global ambassador for DirectTrust establishing collaborative relationships with key industry stakeholders, and oversees the governance of a rapidly growing network for secure, interoperable, health information exchange.
• A 25-year veteran of the healthcare IT industry, Dr. Kibbe was previously the founder of the American Academy of Family Physicians’ Center for Health IT, CEO of the innovative web-based care coordination software company Canopy Systems, and a family physician with 20 years experience in private and academic medical practice in Maine, Texas, and North Carolina.
• Dr. Kibbe is a graduate of Harvard University magna cum laude class of 1972. He completed his medical training at Case Western Reserve University and the University of North Carolina at Chapel Hill, and his business degree at the University of Texas at Austin.
Purpose of this presentation

- This presentation is intended as an introduction to Direct exchange and the roles that DirectTrust plays in governance of its trust framework and national network for health information exchange, and in the context of the HIT Provisions of the 21st Century Cures Act regarding interoperability.
- In a little over 5 years, Direct exchange has grown from a concept into the largest standards-based national network for electronically sharing health data and information that is not vendor-owned, with over 167 million clinical transactions in 2017, up from just 22 million in 2014. Over 350 US EHR vendors’ products now support Direct send and receive, and the network reaches over 1.5 million end-users at 100,000 health care organizations.
- US hospitals alone will produce 9 billion fax pages during 2017: just one example of the long road ahead in the adoption of electronic means of transporting health data to support care and care coordination.
- However, the goal of ubiquitous health care connectivity and interoperability is within sight, and the gains in terms of productivity, better coordination of care, and improvement in health status may soon follow.
Agenda of this presentation

• Why was the Direct Standard developed, how does it work, and who uses it?
• What does DirectTrust, a non-profit trade alliance, do to support Direct exchange?
• What is the DirectTrust network and its current reach?
• What are the highlights of the HIT Provisions of the 21st Century Cures Act, and how does Direct and DirectTrust fit into that context?
The Origins and Purpose of the Direct Standard
April 2010
• ONC launches Direct Project as a simple, secure, scalable way to send health data over the Internet

May 2012
• ONC issues draft RFI for NPRM to establish governance mechanism for NwHIN

February 2009
• HITECH Act, enacted as part of the American Recovery and Reinvestment Act to promote the adoption and meaningful use of health IT

April 2011
• Applicability Statement published
• “Rules of the Road” Workgroup
• HIEs charged with using Direct

May 2012
• DirectTrust incorporates as a 501(6)(c) non-profit trade alliance in order to develop “trust framework” for Direct exchange

March 2013
• ONC establishes Exemplar HIE Governance Program, awards DirectTrust Cooperative Agreement

March 2016
• Federal Health Architecture & DirectTrust agree on enhanced security controls for the federal agencies
• New GTAB established by DirectTrust

December 2016
• Congress passes HIT Provisions of 21st Century Cures Act to ensure interoperable health IT and discourage information blocking

Jan 2018
• ONC issues TEFC part A and part B to meet Cures Act HIT provisions for HIE “query” governance

Jan 2018
• DirectTrust reaches 1.7 million endpoints, and extends PKI trust framework to scale trust for FHIR community.

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The Direct Standard

• The Direct Standard was designed and developed for one purpose and one purpose only:

• To enable a simple, secure, scalable, vendor-neutral and content-agnostic way to transport health data and information over the Internet from one point to another.
Direct Exchange

- Salient features of Direct exchange using the Direct Standard:
  - Uses off the shelf standards and Internet resources such as SMIME/SMTP, DNS, Public Key Infrastructure (PKI), X.509 certificates, etc. easily integrated into health IT systems.
  - First intention was for “push” exchange between providers using different EHRs and caring for same patients.
  - Meant to move data across organizational and health IT vendor borders, e.g. Cerner to EPIC clinicians and administrators.
  - Had to be national in scope and able to “scale,” that is grow exponentially while maintaining only linear or decreasing costs of participation. In other words, display network effects.
DirectTrust’s network has grown to 1.7 million trusted end points in all 50 states, enabled in 350+ EHRs.
According to year-end 2017 metrics, there were more than 167 million Direct message transactions between DirectTrust addresses in 2017, a significant increase over the 2016 total of 98 million transactions. There were more than 45 million Direct messages transmitted during the fourth quarter of 2017 alone.

**Note: 11 of the 38 HISP haven’t reported their data for Q4 2017.**
How Direct Exchange Works
How Direct exchange works

• Direct accounts use addresses to identify trusted end-points
  – Look like email addresses, but Direct is much more than “email”
  – A Direct address bound to a unique X.509 digital certificate is best thought of as a secure end-point identifier for secure health information exchange of any kind.

• An individual or organization may have multiple Direct addresses
• Patients, servers, and devices may also be identified as secure end-points for Direct transport. Never “just email.”
Three separate service providers play roles and together combine to enable Direct exchange.

1. Registration Authority (RA)
   - Compile/Validate Identity and Trust Documentation
   - Identity vetting at a specific level of Assurance, LoA.

2. Certificate Authority (CA)
   - X.509 Certificate Issuance Service
   - Certificate Validation Service
   - Certificate Signing Services
   - Revocation Services
   - The CA and RA enforce the policies specified in the DirectTrust and FBCA Certificate Policy (CP).
   - Credential issued on the basis of RA’s Identity vetting at specific LoA.

3. Health Information Service Provider (HISP)
   - The HISP enforces the policies specified in the DirectTrust HISP Policy (HP), and MUST use accredited RA and CA.
   - The HCO relies on HISP, CA, and RA as accredited trusted agents, and bears ultimate responsibility for HIPAA privacy and security.

Basic services for user: DNS discovery; encryption; certificate signing and validation; send/receive MDNs; provide HISP-side of edge protocol connection compliance with Direct standard.
Exchange via Direct starts with an edge client app, always involves a HISP, and deploys encryption/identity verification.

DrBob@direct.familypractice.com (has been identity vetted, has X.509 Digital certificate bound to address.)

DrSusan@direct.cardiology.com (has been identity vetted, has X.509 Digital certificate bound to address.)
How DirectTrust Works
What is DirectTrust?


• Thirteen member Board of Directors have oversight of 7 standing workgroups, 2 advisory committees, and 5 committees of the Board.

• Liaison Board member from ONC.
DirectTrust’s Trust Framework: The Primary Job of the Organization

- DirectTrust’s Trust Framework is a dynamic and voluntary technical and human system, involving legal, policy, infrastructural and governance components.

- The primary purpose of the Trust Framework is to instill confidence in the security and identity controls all parties apply to their roles in exchange.

- The Trust Framework “scales” trust by making it unnecessary for relying parties to negotiate one-off agreements for trust. It creates a “network of trust.”

- At the heart of DirectTrust’s Trust Framework is its Public Key Infrastructure, PKI.
The DirectTrust Network is a large federation supporting a peer-to-peer network with one-to-many connections.

- 400+ Direct-enabled, ONC certified EHRs & PHRs
- 100,000+ health care organizations
- 50+ HIEs in 20 states
- 2 Federal Agencies
- 1.5 million Direct addresses
- 67 million transactions in 2015, 98+ million in 2016
- Adding 1 million+ transactions per month in 2016
- Estimated 150 million in 2017
Directory and Network Services Expansion in 2016

- Accredited Trust Anchor Bundle for the Private Sector
- Directory Service for Provider Direct Addresses (500K Addresses)
- Interoperability Testing and Reporting Service
- **New** Governmental Trust Anchor Bundle (GTAB) approved by FHA and DirectTrust Board in March 2016
  - GTAB created for Federal and State Agencies, e.g. VA, DoD, CMS, CDC
  - GTAB is a collaborative effort between FHA and DirectTrust
  - The Governmental Trust Anchor Bundle:
    - Hosted and operated by DirectTrust
    - Contains Anchor Certificates that chain up to the FBCA Certificate Authority
    - Private Keys are stored on FIPS 140-2 minimum HSM or are encrypted by a symmetric key stored on the HSM
    - All cryptographic functions using an asymmetric key must be performed on the HSM
    - Only FIPS 140-2 approved algorithms may be used for S/MIME
New Use Cases for Direct Exchange and Remaining Challenges
Direct Interoperability is evolving, adapting, innovating, maturing

New Use Case Examples for Direct interoperability

- Replacement of all fax transmissions where possible
- Substitution of one-off VPNs and other secure one-off connections
- Pharmacy communications with providers
- Long-term and Post-acute care facility exchange with hospitals
- Disease registry data collection from multiple EHRs supporting multiple data content types
- Mobile application support with delivery to any EHR
- Alerts and reminders from HIE to multiple EHR products
- Automation of referrals to State tobacco cessation programs
- Data transport to specialty-specific and federal repositories for safety, quality, and public health reporting
- Automation of CCD to hospital ER when practice’s patients arrives
- Replacement of fax for federal agency referrals and authorizations
- Patient and Consumer Direct accounts and addresses within mHealth, PHR, and social web apps

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Remaining Challenges

1. Lack of and uneven knowledge about how best to deploy Direct exchange, due largely to filtering of information by existing legacy vendors and health IT interests. Many misconceptions remain and need to be addressed through education and best practices outreach.

2. Competition between interoperability technology adherents. Tendency to think of “either/or” instead of “both/and” for complementary standards-based platforms, e.g. Direct and FHIR, eHealthExchange and Direct. Standard components can and should be used together and combined.

3. Inconsistency of EHR vendor support for features and functions to optimize use of Direct exchange. Usability varies from almost none to excellent, depending on EHR vendor’s technical skills, user demand (or lack thereof), and business models viewed as competitive to Direct exchange.

4. Optionality of machine-readable content and payload standards. In particular, C-CDA formatted documents are often mismatched between sender’s and receiver’s needs and expectations.

ALL OF THESE CAN BE AND ARE BEING ADDRESSED. BUT ADDITIONAL EFFORTS WILL ACCELERATE ADOPTION AND USE OF DIRECT EXCHANGE AS A UBIQUITOUS NATIONAL TRANSPORT PLATFORM
21st Century Cures Act: A Large Piece of Legislation

- After almost two years of negotiations the final bill passed the House 392 to 26, and the Senate 94 to 5.
- On December 13, 2016 President Obama signed the 21st Century Cures Act into law.
- The law authorizes a $6.3 billion package of medical innovation bills including:
  - $4.8 billion to the National Institutes of Health (NIH) which includes $1.4 billion for Precision Medicine Initiative;
  - $1.8 billion for Beau Biden Cancer Moonshot initiative; and
  - $1.6 billion for the BRAIN initiative
- Also provides $1 billion in state grants over two years to address opioid abuse and addiction
- Provides $500 million through 2026 to the FDA

25 Sections, 996 pages
• Key HIT provisions of the Cures legislation:
  – Require the Secretary within one year to establish a strategy to reduce administrative and regulatory burdens associated with providers’ use of electronic health records (EHRs). Must include MU, MIPS, APMs, certification, standards.
  – Seek to advance interoperability and curb information blocking.
  – Promote new reporting measures on usability, security, and functionality for EHRs and other HIT and require adherence for certification.
  – Seek to improve patient care and access to health information in EHRs.
  – Require the establishment of a new digital contact index, e.g. a directory, for health care professionals, practices, and facilities.
  – Ensure adequate patient matching to protect privacy and security.
Interoperability

Creates a statutory definition for interoperability as Health IT (HIT) that:

• Enables the secure exchange of electronic health information with, and use of electronic health information from, other HIT without special effort on the part of the user

• Allows for complete access, exchange and use of all electronically accessible health information for authorized use under applicable state or federal law

• Does not constitute information blocking as defined in the Cures legislation
### Timeline for Major Cures HIT Provisions

<table>
<thead>
<tr>
<th>Milestone 1</th>
<th>Milestone 2</th>
<th>Milestone 3</th>
<th>Milestone 4</th>
<th>Milestone 5</th>
<th>Milestone 6</th>
<th>Milestone 7</th>
<th>Milestone 8</th>
<th>Milestone 9</th>
<th>Milestone 10</th>
<th>Milestone 11</th>
<th>Milestone 12</th>
<th>Milestone 13</th>
<th>Milestone 14</th>
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<tr>
<td>ONC convenes HIT Advisory Committee.</td>
<td>Sec. submits MU report to HITAC.</td>
<td>ONC convenes stakeholders to support trusted exchange framework.</td>
<td>Sec. develops strategy and recommendations to reduce regulatory burdens.</td>
<td>Sec. makes as a condition of certification that technology vendors do not block information, have APIs for access, and have tested the real world use of products for interoperability.</td>
<td>Sec. makes as a condition of certification that technology vendors do not block information, have APIs for access, and have tested the real world use of products for interoperability.</td>
<td>Sec. must convene stakeholders for the purpose of developing the reporting criteria for EHR Reporting Program, and award grants to implement a process for reporting.</td>
<td>Comptroller Gen. conducts study to ensure appropriate patient matching to electronic health information.</td>
<td>ONC publishes on its website trusted exchange framework and common agreement.</td>
<td>CMS must report on suitability and barriers to telehealth services.</td>
<td>Sec. recommends on voluntary certification of health IT used by pediatricians.</td>
<td>Comptroller Gen. reports to Congress on patient access to PHI, incl. barriers and difficulties experienced.</td>
<td>ONC publishes on its website health info networks that have adopted common trust agreement.</td>
<td>Comptroller reports to Congress on patient matching.</td>
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</tbody>
</table>

**2017**
- **July 2017**: Milestone 1, Milestone 3
- **Jan 2018**: Milestone 2, Milestone 4
- **July 2018**: Milestone 5, Milestone 6
- **Jan 2019**: Milestone 7, Milestone 8

**2019**
- **2019**: Milestone 9, Milestone 10, Milestone 11, Milestone 12, Milestone 13, Milestone 14

**Within 3 years the Sec. shall directly or through partnership with a private entity establish a provider digital contact index for providers and health facilities.**

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The Mandala of Cures
HIT Provisions

Continuity with Recent Past

Additional New Regulations

MD-Friendly Deregulation

Off in a New Direction
Stakeholders who can use the Trusted Exchange Framework

**HEALTH INFORMATION NETWORKS**

**FEDERAL AGENCIES**
Federal, state, tribal, and local governments

**INDIVIDUALS**
Patients, caregivers, authorized representatives, and family members serving in a non-professional role

**PROVIDERS**
Professional care providers who deliver care across the continuum, not limited to but including ambulatory, inpatient, long-term and post-acute care (LTPAC), emergency medical services (EMS), behavioral health, and home and community based services

**PUBLIC HEALTH**
Public and private organizations and agencies working collectively to prevent, promote and protect the health of communities by supporting efforts around essential public health services

**PAYERS**
Private payers, employers, and public payers that pay for programs like Medicare, Medicaid, and TRICARE

**TECHNOLOGY DEVELOPERS**
Organizations that provide health IT capabilities, including but not limited to electronic health records, health information exchange (HIE) technology, analytics products, laboratory information systems, personal health records, Qualified Clinical Data Registries (QCDRs), registries, pharmacy systems, mobile technology, and other technology that provides health IT capabilities and services

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How Will the Trusted Exchange Framework Work?

RCE provides oversight and governance for Qualified HINS.

Qualified HINs connect directly to each other to serve as the core for nationwide interoperability.

QHINs connect via connectivity brokers.

Each Qualified HIN represents a variety of networks and participants that they connect together, serving a wide range of end users.

READ MORE: QHINs in Part B, Section 2

READ MORE: Connectivity Broker Capabilities in Part B, Section 3
Interoperability Matrix
Contact Information

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913.205.7968
AMA Digital Health and Integrated Health Model Initiative (IHMI) Overview

Physician’s EHR Coalition (PEHRC)

HIMSS18
The American Medical Association

MEDICINE &
PUBLIC HEALTH

We promote the art and science of medicine and the betterment of public health.

PHYSICIAN & PATIENT
ADVOCACY

We are the largest physician advocacy organization in the United States
- Voice of the physician since 1847
- Membership organization that represents more than 190 state/national & specialty medical associations

BUSINESS SOLUTIONS

We address the most pressing health care industry needs through innovative data solutions, products, and services.
The AMA: Our Strategic Approach

1. **Vital practice resources**
   - AMA StepsForward™ practice improvement strategies
   - MACRA/QPP Action Kit and Payment Model Evaluator
   - FREIDA®: AMA Residency & Fellowship Database™
   - GME competency training
   - CPT® for accurate diagnostic tracking and reimbursement
   - Resources to achieve improvements in digital medicine

2. **Lifelong professional development**
   - Partnering with 32 medical schools to transform medical education
   - *JAMA*® clinical research journals
   - Initiatives to combat physician burnout
   - AMA Education Center
   - GME Competency Education Program
   - AMA Code of Medical Ethics
   - AMA Journal of Ethics
   - Career Planning Resource

3. **Improving the health of the nation**
   - Addressing the leading chronic causes of death and disability
   - Advocating for coverage of preventive services
   - Reducing health care disparities
   - Confronting the opioid epidemic
   - Reducing unnecessary regulatory burdens
   - Enhancing personalized medicine
   - Addressing prescription drug costs
   - Advancing public health policy and positions
2018 Digital Health Objectives

Address current frustrations

- 2:1 time on the EHR/admin burdens affecting burnout and patient/physician relationship
- 300k digital health solutions = wild wild west
- Lack of physician voice in solutions

Accelerate the adoption of effective solutions for improved outcomes

- Share guidance (research, guidelines, best practices)
- Convene the industry to move effective solutions from pilots to the real world of practicing physicians
- A need to manage chronic disease in the “wild” outside of the four walls of the clinic
Current State: Complex and Chaotic Landscape
A Focus on Digital Health: Listening to Physicians

What attracts physicians to digital tools? What are their requirements for adoption?

Source: AMA Digital Health Survey 2016
# Enthusiasm Based on Taking Better Care of Patients

<table>
<thead>
<tr>
<th>Feature</th>
<th>Works in Progress/ Early Adopters</th>
<th>Established Solutions/ Early Majority</th>
<th>Mainstream Innovation/ Late Majority</th>
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<tbody>
<tr>
<td>Tele-visits / virtual visits</td>
<td>36</td>
<td>45</td>
<td>53</td>
</tr>
<tr>
<td>Remote monitor for efficiency</td>
<td>14</td>
<td>12</td>
<td>42</td>
</tr>
<tr>
<td>Remote monitor &amp; mgt for improved care</td>
<td>13</td>
<td>26</td>
<td>53</td>
</tr>
<tr>
<td>Clinical decision support</td>
<td>13</td>
<td>28</td>
<td>Current using</td>
</tr>
<tr>
<td>Patient engagement</td>
<td>26</td>
<td>53</td>
<td>Current using</td>
</tr>
<tr>
<td>Point of care/ workflow enhancement</td>
<td></td>
<td>53</td>
<td>Current using</td>
</tr>
<tr>
<td>Consumer access to clinical data</td>
<td></td>
<td></td>
<td>53</td>
</tr>
</tbody>
</table>

Source: AMA Digital Health Survey 2016
The digital health landscape comes with many questions. The AMA has answers.
AMA Physician Innovation Network

- Physicians are interested in making their voices heard for the development of health tech solutions
- Health tech companies are looking for feedback but currently difficult to obtain
- AMA platform easily connects physicians and health tech companies who are looking to collaborate for improved solutions
Xcertia

• Today there are no comprehensive, industry-vetted guidelines for the 300,000+ mobile health apps and solutions in the market.

• Xcertia is a multi-stakeholder collaboration dedicated to addressing this issue.

• Focused on improving the quality, safety and effectiveness of mobile health applications to improve patient care.

• Organizations interested in leading the future of mobile health are invited to join.
Digital Medicine Payment Advisory Group (DMPAG)

• Supports the integration of digital medicine services into physician practices while ensuring the quality of patient care.

• This group of 15 nationally recognized experts is responsible for identifying barriers to digital medicine adoption and proposing comprehensive solutions revolving around coding, payment, coverage and more.

• Increasing coverage requires a concerted effort by knowledgeable professionals as well as input, such as pertinent use cases and clinical data that demonstrate the efficiencies and clinical benefits of digital medicine.

• Digital medicine presents an opportunity to improve access and to offer cost-effective medical care to a large swath of patients with diverse needs.
Unleash a new era of better, more efficient patient care
Data is the Problem

• Critical information on patient function, state, goals, as well as patient and device generated data is inaccessible

• Healthcare data is fragmented, incomplete, incompatible, variable by system and not always machine readable

• Current data models are created for a segment of the industry (eg. clinical research)

• Other industries have solved their data problems

• Why not healthcare?
A Common Data Model Solution

• Created for and available to all stakeholders at no cost, sustained by paid resources, and incorporates expert input

• A medical information model and master coding system that:
  • Integrates existing code sets;
  • Adds function, state, patient goals, descriptors and other critical data elements;
  • Organizes data in a shared context;
  • Supports expression of wellness and population health;
  • Enables semantically interoperable technical solutions and care models; and
  • Evolves based on real world use and feedback.
A Common Data Model Solution

DEVELOPMENT AND ENHANCEMENT OF THE MODEL
With input from the IHMI Communities and Clinical Validation Process

1. CODING LAYER
Expresses data elements with structured concepts leveraging existing code sets and adding essential data elements

2. CONTEXT LAYER
Expresses coding layer concepts in context of use

3. KNOWLEDGE LAYER
Expresses complex meaning using coding and integration layers
IHMI Continuous Learning System
Informing, sharing and learning together

COLLABORATIVE PLATFORM
- Focus on costly & burdensome areas
- Identify best science & practices

COMMON DATA MODEL
- Encode in a common data model
- Configure model & reference value set

Distribute model & collect usage data

CLINICAL VALIDATION PROCESS
- Evaluate clinical applicability of submitted content
- Validate with peer review panel

Specify data elements & relationships

FEEDBACK LOOPS

MARKET-INFORMED PROCESS

AMA
Integrated Health Model Initiative
Prioritizing Efforts

Start with defining wellness, hypertension, diabetes, asthma…

Disease burden
- Morbidity & mortality
- Years of life lost
- Quality of life
- Risk factors

Economic burden
- Payer expense
- Lost productivity
- Out-of-pocket expenses

Societal burden
- Public health priority
- Social determinants of health
- Disruptive innovations

Community informed roadmap for the future…
Transformational Opportunities

- Digital Medicine
- Clinical Research
- Predictive Analytics
- Risk Stratification
- Resource Utilization
- Collab Care & Population Health
- Payment Innovation
- Outcome Computation
- Quality Reporting

*AMA Integrated Health Model Initiative*
IHMI is not...

• IHMI is *not a mandated standard*; it is a market-driven process.

• IHMI is *not a registry*; it is a collaborative platform for improving information across health care.

• IHMI is *not a repository for collecting or storing patient health data*; a component of IHMI is a data model that can be used to structure data across technical solutions and care models.

• IHMI is *not another code set*; it is a process for identifying and structuring meaningful and essential data elements, using existing code sets and adding essential gap filling codes where needed.
Why the AMA?

• AMA can convene medicine and technology around market-driven solutions that are meaningful to clinical practice

• AMA represents the interests of patients and physicians across the house of medicine

• AMA serves as an honest broker, important for sustainability of an interoperability solution

• AMA has a proven track record as an organization with stamina and sustainable leadership
Join us at ama-ihmi.org – Questions to ihmi@ama-assn.org
What They’re Saying……

One of our primary goals is to continue to develop a patient-centered approach to heart and stroke care. This new collaboration will ensure that patients receive the best care throughout their journey by providing a holistic view of a patient’s health data to health care providers along the way. By sharing data, we not only create a better experience for the patient, but, ultimately, better outcomes, more lives saved and an improved quality of life.

- Meighan Girgus, Chief Marketing and Programs Officer
American Heart Association

Ensuring the accuracy and completeness of the information used to manage a person’s care is a priority for Cerner, so we are happy to support this AMA initiative to improve the semantics of clinical data models. This represents a bold attempt to advance an important aspect of interoperability.

- David McCallie, M.D., SVP Medical Informatics
Cerner

A proliferation of data in health care has made informatics an essential component to the practice of modern medicine, and AMIA will ensure that IHMI benefits from the latest in informatics science, practice, and education. We are excited to bring our members’ wealth of knowledge to IHMI so that our national investment in digitizing care can lead to improved health outcomes.

- Douglas H. Fridsma, MD, PhD, FACP, FACMI, President and CEO
American Medical Informatics Association

This important and novel initiative aligns with our mission to help healthcare providers make essential connections and gain confidence in the decisions they make. Participation in this collaborative supports our goal to help providers improve patient outcomes and experience, reduce cost, and enhance physician and care team satisfaction.

- William Kassler, MD, Deputy Chief Health Officer
IBM Watson Health

I am excited about IHMI because it builds on the foundation of interoperability standards that are being created by HL7, LOINC, and SNOMED International. If we persist, that approach will lead to the ability to exchange medical knowledge as executable software rather than as journal articles. If we can do it, it will be a historic evolutionary step for medicine.

- Stan Huff, M.D., Chief Medical Informatics Officer
Intermountain Healthcare

The IHM initiative complements the approach that SNOMED International embodies regarding continuous learning and collaboration. Committed to the unambiguous exchange of clinical information across all health systems, services and products through terminology, SNOMED International is excited to contribute to IHM’s collaborative community and its pursuit of safe, effective and patient-driven healthcare.

- Don Sweete, Chief Executive Officer
SNOMED International
IHMI Media Coverage

Leading Organizations Highlight Collaboration with the AMA’s IHMI
For immediate release: Oct 16, 2017

AMA to Unleash a New Era of Patient Care
For immediate release: Oct 16, 2017

27 Media outlets in 30 hours post press release
A Long Journey

- Understand meaningful change requires resources and stamina
- Engage all stakeholders to address costly and burdensome diseases
- Focus on market problems and white space opportunities
- Develop demonstration projects to deliver benefits and proof points
- Iterate using real world experience and feedback
- Support the mission of IHMI to improve access to meaningful data in a semantically interoperable way
Understanding The Draft Trusted Exchange Framework

Genevieve Morris, Principal Deputy National Coordinator, ONC
March 6, 2018
What is the Draft Trusted Exchange Framework?
Part A—Principles for Trusted Exchange

General principles that provide guardrails to engender trust between Health Information Networks (HINs). Six (6) categories:

» **Principle 1 - Standardization:** Adhere to industry and federally recognized standards, policies, best practices, and procedures.

» **Principle 2 - Transparency:** Conduct all exchange openly and transparently.

» **Principle 3 - Cooperation and Non-Discrimination:** Collaborate with stakeholders across the continuum of care to exchange electronic health information, even when a stakeholder may be a business competitor.

» **Principle 4 - Security and Patient Safety:** Exchange electronic health information securely and in a manner that promotes patient safety and ensures data integrity.

» **Principle 5 - Access:** Ensure that patients and their caregivers have easy access to their electronic health information.

» **Principle 6 - Data-driven Accountability:** Exchange multiple records at one time to enable identification and trending of data to lower the cost of care and improve the health of the population.

Part B—Minimum Required Terms and Conditions for Trusted Exchange

A minimum set of terms and conditions for the purpose of ensuring that common practices are in place and required of all participants who participate in the Trusted Exchange Framework, including:

» Common authentication processes of trusted health information network participants;

» A common set of rules for trusted exchange;

» A minimum core set of organizational and operational policies to enable the exchange of electronic health information among networks.
Goals of the Draft Trusted Exchange Framework

**Goal 1**
Build on and extend existing work done by the industry

The Draft Trusted Exchange Framework recognizes and builds upon the significant work done by the industry over the last few years to broaden the exchange of data, build trust frameworks, and develop participation agreements that enable providers to exchange data across organizational boundaries.

**Goal 2**
Provide a single “on-ramp” to interoperability for all

The Draft Trusted Exchange Framework provides a single “on-ramp” to allow all types of healthcare stakeholders to join any health information network they choose and be able to participate in nationwide exchange regardless of what health IT developer they use, health information exchange or network they contract with, or where the patients’ records are located.

**Goal 3**
Be scalable to support the entire nation

The Draft Trusted Exchange Framework aims to scale interoperability nationwide both technologically and procedurally, by defining a floor, which will enable stakeholders to access, exchange, and use relevant electronic health information across disparate networks and sharing arrangements.

**Goal 4**
Build a competitive market allowing all to compete on data services

Easing the flow of data will allow new and innovative technologies to enter the market and build competitive, invaluable services that make use of the data.

**Goal 5**
Achieve long-term sustainability

By providing a single “on-ramp” to nationwide interoperability while also allowing for variation around a broader set of use cases, the Draft Trusted Exchange Framework ensures the long-term sustainability of its participants and end-users.
Who can use the Trusted Exchange Framework?
Stakeholders who can use the Trusted Exchange Framework

**HEALTH INFORMATION NETWORKS**

**FEDERAL AGENCIES**
Federal, state, tribal, and local governments

**INDIVIDUALS**
Patients, caregivers, authorized representatives, and family members serving in a non-professional role

**PROVIDERS**
Professional care providers who deliver care across the continuum, not limited to but including ambulatory, inpatient, long-term and post-acute care (LTPAC), emergency medical services (EMS), behavioral health, and home and community based services

**PUBLIC HEALTH**
Public and private organizations and agencies working collectively to prevent, promote and protect the health of communities by supporting efforts around essential public health services

**PAYERS**
Private payers, employers, and public payers that pay for programs like Medicare, Medicaid, and TRICARE

**TECHNOLOGY DEVELOPERS**
Organizations that provide health IT capabilities, including but not limited to electronic health records, health information exchange (HIE) technology, analytics products, laboratory information systems, personal health records, Qualified Clinical Data Registries (QCDRs), registries, pharmacy systems, mobile technology, and other technology that provides health IT capabilities and services
The Trusted Exchange Framework aims to create a technical and governance infrastructure that connects Health Information Networks together through a core of Qualified Health Information Networks.
What is a Health Information Network?

Health Information Networks (HINs) are an Individual or Entity that:

1. Determines, oversees, or administers policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities;

2. Provides, manages, or controls any technology or service that enables or facilitates the exchange of electronic health information between or among two or more unaffiliated individuals or entities; or

3. Exercises substantial influence or control with respect to the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.
What is a Qualified Health Information Network?

A Qualified Health Information Network (Qualified HIN) must meet ALL of the requirements of a HIN. In addition, it must also:

- Be able to locate and transmit ePHI between multiple persons and/or entities electronically;
- Have mechanisms in place to impose Minimum Core Obligations and to audit Participants’ compliance;
- Have controls and utilize a Connectivity Broker service;
- Be participant neutral; and
- Have Participants that are actively exchanging the data included in the USCDI in a live clinical environment.
What are the benefits of the Trusted Exchange Framework?
For Qualified HINs and HINs the Trusted Exchange Framework will:

- Give HINs and their participants access to more data on the patients they currently serve. This will enhance care coordination and care delivery use cases.

- The Trusted Exchange Framework ensures that there is no limitation to the aggregation of data that is exchanged among Participants. This will allow organizations, including Health IT Developers, HINs, QCDRs, and other registries to use the Trusted Exchange Framework to obtain clinical data from providers and provide analytics services. (Note that appropriate BAs must be in place between the healthcare provider and analytics provider.)
For Health Systems and Ambulatory Providers the Trusted Exchange Framework will:

Enable them to join one network and have access to data on the patients they serve regardless of where the patient went for care.

- This enables safer, more effective care, and better care coordination.

Enable them to eliminate one off and point-to-point interfaces

- This will allow providers and health systems to more easily work with third parties, such as analytics products, care coordination services, HINs, Qualified Clinical Data Registries (QCDRs), and other registries. (Note that appropriate BAs must be in place between the healthcare provider and analytics provider.)
For Patients and Their Caregivers, the Trusted Exchange Framework will:

Enable them to find all of their health information from across the care continuum, even if they don’t remember the name of the provider they saw.

- This enables patients and their caregivers to participate in their care and manage their health information.
How will the Trusted Exchange Framework work?
Recognized Coordinating Entity (RCE)

Recognized Coordinating Entity

The RCE is the entity selected by ONC that will enter into agreements with HINs that qualify and elect to become Qualified HINs in order to impose, at a minimum, the requirements of the Common Agreement set forth herein on the Qualified HINs and administer such requirements on an ongoing basis as described herein.

The RCE will act as a governance body that will operationalize the Trusted Exchange Framework by incorporating it into a single, all-encompassing Common Agreement to which Qualified HINs will agree to abide. In its capacity as a governance body, the RCE will be expected to monitor Qualified HINs compliance with the final TEFCA and take actions to remediate non-conformity and non-compliance by Qualified HINs, up to and including the removal of a Qualified HIN from the final TEFCA and subsequent reporting of its removal to ONC.

The RCE will also be expected to work collaboratively with stakeholders from across the industry to build and implement new use cases that can use the final TEFCA as their foundation, and appropriately update the TEFCA over time to account for new technologies, policies, and use cases.

READ MORE: How Will it Work?
Recognized Coordinating Entity (RCE)

Process for Recognizing Entity
ONC will release an open, competitive Funding Opportunity Announcement (FOA) in spring 2018 to award a single multi-year Cooperative Agreement to a private sector organization or entity. The RCE will need to have experience with building multi-stakeholder collaborations and implementing governance principles in order to be eligible to apply for the Cooperative Agreement.

Expectations for Entity
ONC will work with the RCE to incorporate the Trusted Exchange Framework into a single Common Agreement to which Qualified HINs and their participants voluntarily agree to adhere.

The RCE will have oversight, enforcement, and governance responsibilities for each of the Qualified HINs who voluntarily adopt the final TEFCA.

READ MORE: How Will it Work?
A Qualified HIN (QHIN) is a network of organizations working together to share data. QHINs will connect directly to each other to ensure interoperability between the networks they represent.

A Connectivity Broker is a service provided by a Qualified HIN that provides all of the following functions with respect to all Permitted Purposes: master patient index (federated or centralized); Record Locator Service; Broadcast and Directed Queries, and EHI return to an authorized requesting Qualified HIN.

A Participant is a person or entity that participates in the QHIN. Participants connect to each other through the QHIN, and they access organizations not included in their QHIN through QHIN-to-QHIN connectivity. Participants can be HINs, EHR vendors, and other types of organizations.

An End User is an individual or organization using the services of a Participant to send and/or receive electronic health info.
How Will the Trusted Exchange Framework Work?

RCE provides oversight and governance for Qualified HINS.

Qualified HINs connect directly to each other to serve as the core for nationwide interoperability.

QHINs connect via connectivity brokers.

Each Qualified HIN represents a variety of networks and participants that they connect together, serving a wide range of end users.

READ MORE: QHINs in Part B, Section 2

READ MORE: Connectivity Broker Capabilities in Part B, Section 3
Qualified HIN Requirements Clarifications

- A minimum floor in the areas where there is currently variation between HINs that causes a lack of interoperability.
- Obligation to respond to Broadcast or Directed Queries for all the Permitted Purposes outlined in the Trusted Exchange Framework.
- Qualified HINs must exchange all of the data specified in the USCDI to the extent such data is then available and has been requested.
- Base set of expectations for how Qualified Health Information Networks connect with each other.

- A full end-to-end agreement that would be a net new agreement.
- No expectation that every HIN will serve same constituents or use cases. (i.e. no requirement that Qualified HINs initiate Broadcast or Directed Queries for all of the Permitted Purposes outlined in the Trusted Exchange Framework)
- Not dictating internal technology or infrastructure requirements.
- No limitation on additional agreements to support uses cases other than Broadcast Query and Directed Query for the Trusted Exchange Framework specified permitted purposes.
What use cases are covered under the Trusted Exchange Framework?
Use Cases

**Broadcast Query**
Sending a request for a patient’s Electronic Health Information (EHI) to all Qualified HINs to have data returned from all organizations who have it.
Supports situations where it is unknown who may have Electronic Health Information about a patient.

**Directed Query**
Sending a targeted request for a patient’s Electronic Health Information to a specific organization(s).
Supports situations where you want specific Electronic Health Information about a patient, for example data from a particular specialist.

**Population Level Data**
Querying and retrieving Electronic Health Information about multiple patients in a single query.
Supports population health services, such as quality measurement, risk analysis, and other analytics.

READ MORE: Broadcast and Directed Queries - Part B, Section 5.4 and Section 3
READ MORE: Population level data - Part B, Section 8
The USCDI establishes a minimum set of data classes that are required to be interoperable nationwide and is designed to be expanded in an iterative and predictable way over time. Data classes listed in the USCDI are represented in a technically agnostic manner.

1. USCDI v1—Required—CCDS plus Clinical Notes and Provenance
2. Candidate Data Classes—Under consideration for USCDI v2
3. Emerging Data Classes—Begin evaluating for candidate status
As the USCDI expands, Qualified HINs and their Participants will be required to upgrade their technology to support the data specified in the USCDI.

Some Candidates will be Accepted to USCDI
Some Candidates Require Further Work
Some Emerging Elements Become Candidates
Some Emerging Require Further Work

https://www.healthit.gov/sites/default/files/draft-uscdi.pdf
What privacy and security protections does the Trusted Exchange Framework guarantee?
Identity proofing is the process of verifying a person is who they claim to be. The Trusted Exchange Framework requires identity proofing (referred to as the Identity Assurance Level (IAL) in SP 800-63A).

**End Users and Participants** Each Qualified HIN shall require proof of identity for Participants and participating End Users at a minimum of IAL2 prior to issuance of credentials.

**Individuals** Each Qualified HIN shall require its End Users and Participants to proof the identity for Individuals at a minimum of IAL2 prior to issuance of credentials. Individuals must provide strong evidence of their identity.

<table>
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<th>IAL 2 REQUIREMENT</th>
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| **Evidence**      | • One (1) piece of SUPERIOR or STRONG evidence; OR  
|                    | • Two (2) pieces of STRONG evidence; OR  
|                    | • One (1) piece of STRONG evidence plus two (2) pieces of ADEQUATE evidence |
| **Validation**    | • Each piece of evidence must be validated with a process able to achieve the same strength as the evidence presented.  
|                    | • Validation against a third-party data service SHALL only be used for one piece of presented identity evidence. |
| **Address Confirmation** | • The Credential Service Provider (CSP) SHALL confirm address of record through validation of the address contained on any supplied, valid piece of identity evidence. |

* Full IAL2 requirements can be found at [www.nist.gov](http://www.nist.gov).
Qualified HINs, Participants, or End Users are responsible for proofing Individuals at the IAL2 level, HOWEVER:

**Trusted Referee and Authoritative Source:** In instances where the individual enrolling cannot meet the identity evidence requirements specified, organization staff may act as a trusted referee, allowing them to use personal knowledge of the identity of patients when enrolling patients as subscribers to assist in identity proofing the enrollee.

**Antecedent Event:** Staff may also act as authoritative sources by using knowledge of the identity of the individuals (e.g., physical comparison to legal photographic identification cards such as driver’s licenses or passports, or employee or school identification badges) collected during an antecedent, in-person registration event.

For example, IAL2 identity proofing for an Individual can be accomplished by two of the following:

1. Physical comparison to legal photographic identification cards such as driver’s licenses or passports, or employee or school identification badges,

2. Comparison to information from an insurance card that has been validated with the issuer, e.g., in an eligibility check within two days of the proofing event, and

3. Comparison to information from an electronic health record (EHR) containing information entered from prior encounters.

**READ MORE:** Part B, Section 6.2.4
Privacy/Security: Authentication

Digital authentication is the process of establishing confidence in a remote user identity communicating electronically to an information system. NIST draft SP 800-63B refers to the level of assurance in authentication as the Authenticator Assurance Level (AAL). Federal Assurance Level (FAL) refers to the strength of an assertion in a federated environment, used to communicate authentication and attribute information (if applicable) to a relying party (RP).

Each Qualified HIN shall authenticate End Users, Participants, and Individuals at a minimum of AAL2, and provide support for at least FAL2 or, alternatively, FAL3.

Connecting to a Qualified HIN or one of its Participant will require **two-factor authentication**. A list of acceptable second factors (in addition to a username and password) can be found at https://pages.nist.gov/800-63-3/sp800-63b/sec4_aal.html.

READ MORE: Part B, Section 6.2.5
When will the Trusted Exchange Framework be implemented?