Consent Policy Design Group

Meeting 1
March 26, 2019

Facilitated by:
Michael Matthews, CedarBridge Group
Dr. Ross Martin, CedarBridge Group

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Agenda

Agenda Item	Time
Welcome	1:00 pm
Introductions and participant opening comments	1:05 pm
Overview of Consent Design Group workplan	
• Meeting schedule and desired outcomes	1:15 pm
• Role of the Consent Design Group	1:20 pm
Review of federal and state regulatory landscape	1:25 pm
Open discussion	1:50 pm
Wrap-up and meeting adjournment	2:00 pm

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The Support Team

State of Connecticut

Allan Hackney

Health Information Technology Officer

Chair, HIT Advisory Council

CedarBridge Group

Carol Robinson

Michael Matthews, MSPH

Ross Martin, MD, MHA

Chris Robinson

Velatura

Tim Pletcher, DHA, MS

Lisa Moon, PhD, RN

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The Consent Design Group

- Stacy Beck, RN, BSN* – Anthem / Clinical Quality Program Director
- Pat Checko, DrPH* – Consumer Advocate
- Carrie Gray, MSIA – UConn / HIPAA Security Officer
- Susan Israel, MD – Patient Privacy Advocate / Psychiatrist
- Rob Rioux, MA* – CHCACT / Network Director
- Rachel Rudnik, JD – UConn / AVP, Chief Privacy Officer
- Nic Scibelli, MSW* – Wheeler Clinic / CIO

* Health IT Advisory Council Member

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Consent Policy Design Group – High-Level Work Plan

Meeting Focus	Meeting Objectives
Meeting 1 – 4/9/2019 1pm – 2pm Kickoff and orientation	• Review and discuss project scope and proposed process for achieving desired outcomes • Orientation on relevant policies and procedures and semantic alignment / shared understanding of key terms
Meeting 2 – 4/23/2019 1pm – 2pm Current consent policies	• Establish understanding around current state of consent policies in Connecticut and bordering states • Consider draft language for a HIPAA TPO consent policy for recommendation to Advisory Council
Meeting 3 – 5/7/2019 1pm – 2pm Focus on TPO consent draft	• Review proposed process for the development of a consent policy framework, based on HIE use case requirements • Discuss stakeholder engagement and communication needs
Meeting 4 – 5/21/2019 1pm – 2pm Matching use cases to consent model	• Review and discuss received input from Advisory Council or other stakeholders • Review use cases where individual consent is required by state or federal law, or areas of ambiguity
Meeting 5 – 6/4/2019 1pm – 2pm Use Case A discussion	• Discuss the pros/cons of a statewide vs. HIE Entity consent policy framework to determine scope • Consent policy discussion – use case A
Meeting 6 – 6/18/2019 1pm – 2pm Use Case B discussion	• Consent policy discussion – use case B • Discuss workflows that could provide individuals with information and the ability to manage preferences
Meeting 7 – 7/9/2019 1pm – 2pm Review draft consent framework recommendations – structure and process	• Structure and process for ongoing consent policy development and management • Develop draft recommendations for consent policy framework
Meeting 8 – 7/23/2019 1pm – 2pm Vote on draft recommendations	• Finalize and approve recommendations • Discuss stakeholder / general population engagement and communication process

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Role of the Consent Policy Design Group

- Analyze existing consent policies from other states, review relevant policies and legislation, and discuss issues and barriers to health information exchange.
- Develop and recommend an initial approach to patient consent in support of the first wave of recommended HIE use cases under HIPAA TPO.
- Recommend an ongoing process and structure for evolving the consent model for supporting the HIE Entity and future use cases.

Consent Policy Design Process

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Consent Policy Design Group

Level-setting discussion points

- The patient is the “North Star” in all our deliberations.
- Consent policies should be developed in a flexible way to allow for adaptations over time, as the regulatory environment will continue to change.
- There is an immediate-term need for a consent policy that aligns with the current HIPAA requirements and permissions for sharing personally identifiable information (PII) for treatment, payment, and healthcare operations.
- A consent management solution that gives individuals the ability to manage their consent preferences will need to fit within the workflows of provider organizations as well as meet the needs of consumers/patients.
- Consent policies must consider liability risks for all parties involved in the HIE Entity.

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Consent design is more than Opt-In vs. Opt-Out

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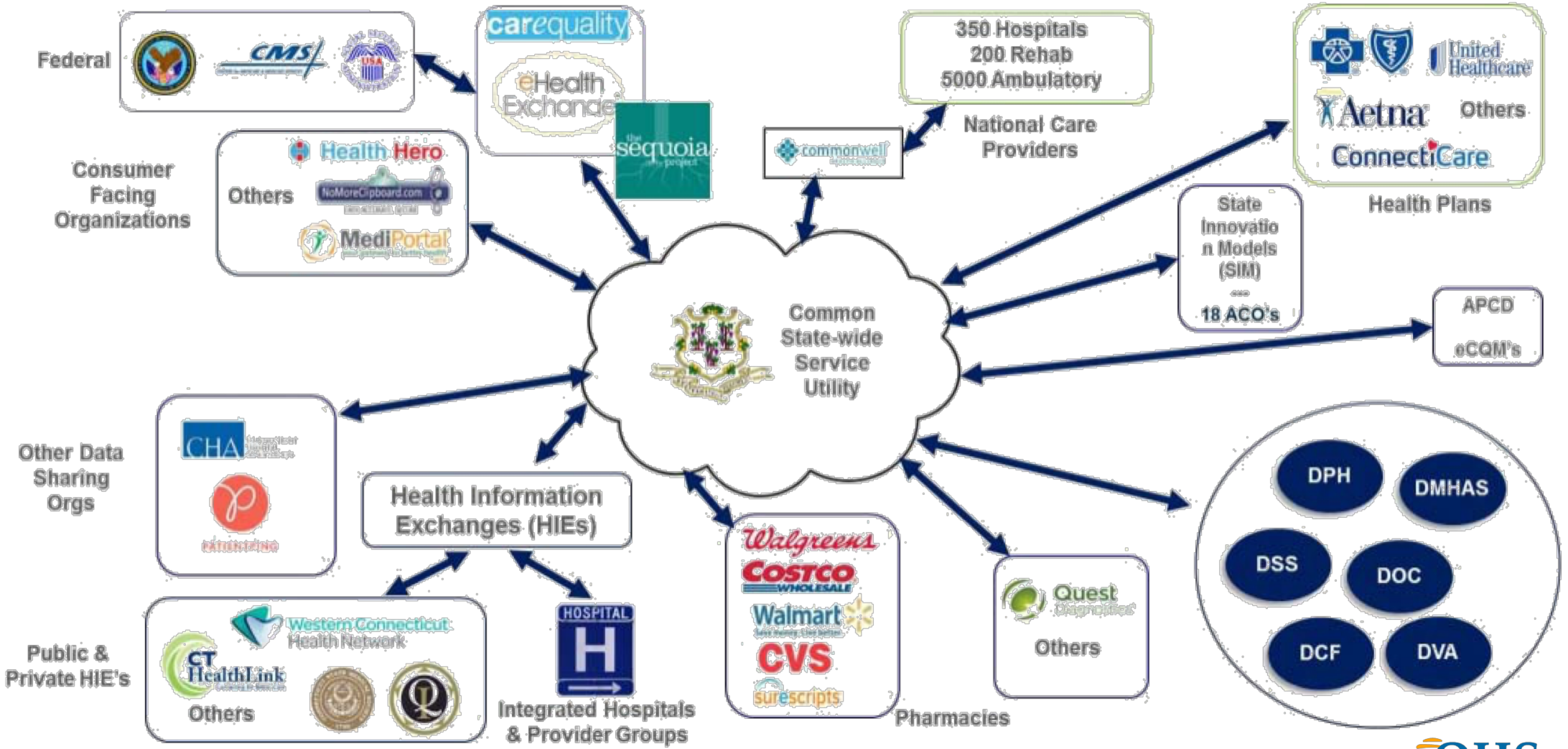
Policy Support for Use Cases

Wave 1 Use Cases and Associated Tasks	
eCQM	• *Procurement and implementation*
IIS (Submit/Query)	• *Implementation and integration with Public Health Reporting; procurement*
Longitudinal Health Record	• *Leverage eHealth Exchange, CareQuality, and CommonWell* • *Implement core services (e.g. master person index and health provider directory)*
Public Health Reporting	• *Assess potential to leverage/expand AIMS* • *Implement expanded data elements, onboarding, and technical assistance*
Clinical Encounter Alerts	• *Finalize business and functional requirements* • *Procurement / contracting (including leverage existing assets)*
Image Exchange	• *Finalize business and functional requirements*

Wave 2 Use Cases and Associated Tasks	
Medical Reconciliation	• *Implement program for process re-design and supporting technology*
MOLST / Advance Directives	• *Partner with existing MOLST Task Force and Advisory Committee for assessment of technology value-add and the value of a complimentary AD Registry*
Patient Portal	• *Plan for rollout after implement*
Population Health Analytics	• *Plan for rollout after eCQM repo*

Future Use Cases	
Bundle Management	Lab Results Delivery
Care Coordination: Care Plan Sharing	Life Insurance Underwriting
Care Coordination: Referral Management	Medical / Lab Orders
Care Coordination: Transitions of Care	Medical Orders / Order Management
CHA Dose Registry	Opioid Monitoring and Support Services
Disability Determination	Patient-generated Data
eConsult	Research and Clinical Trials
Emergency Department Super-utilizers	Social Determinants of Health
Emergency Medical Services (EMS)	Wounded Warriors
Genomics	

Network of Networks



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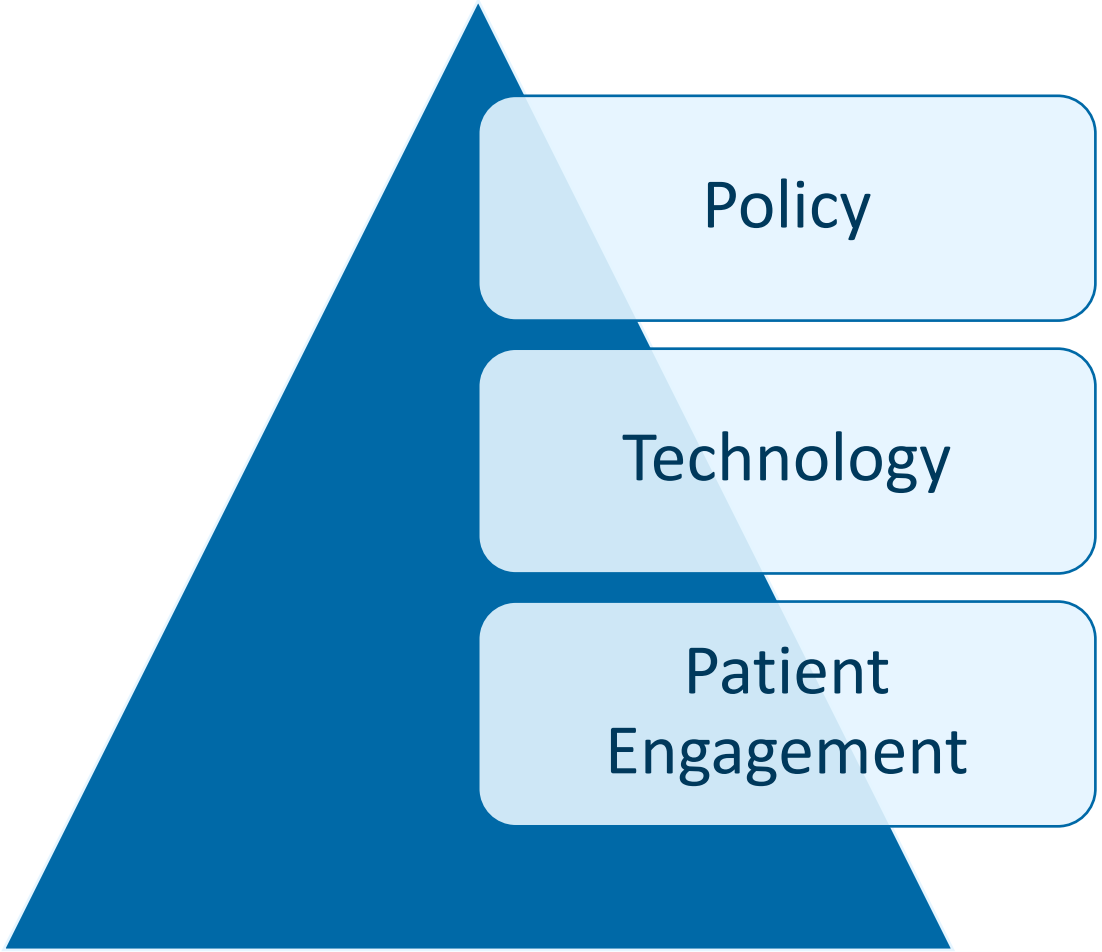
Consent requires multiple elements…



What are the Feds thinking?

- Recent federal laws, regulations, proposed rules, and publications set the frame for the future of health information exchange
  - The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
  - The Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH)
  - NEW:

ONC (1/5/2018)	Draft Trusted Exchange Framework (TEFCA)
HHS (12/14/2018)	Request for Information on updates to HIPAA
CMS (2/11/2019)	NPRM on the 21st Century Cures Act: Interoperability and Patient Access Proposed Rule (and related RFIs)
ONC (3/4/2019)	NPRM on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

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What are the Feds thinking? Major themes

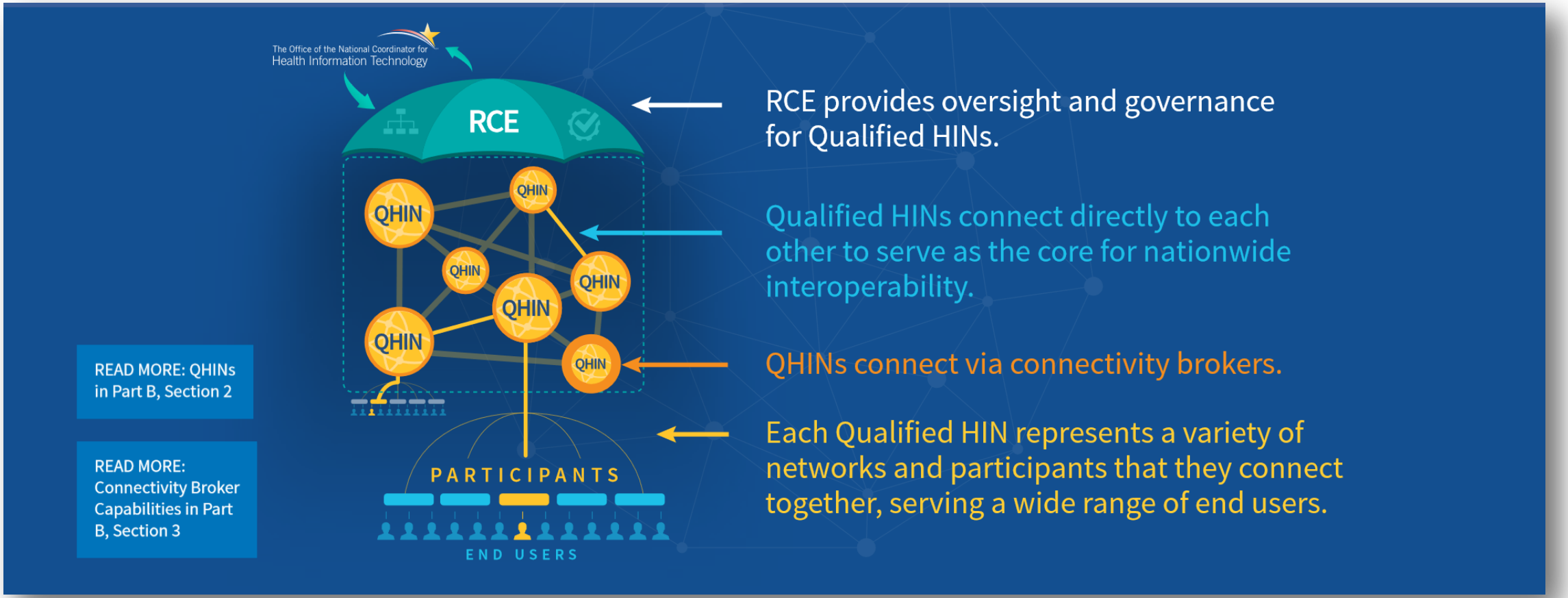
- **Less:** Specific functionality requirements within the EHR (e.g., medication list).
- **More:** Core interoperability and **data flow** capabilities (e.g., APIs).
- Heavy push toward **standards-based APIs** (Application Programming Interfaces), i.e., HL7 FHIR®, to make interoperability simpler and faster to implement. For providers, this means that a certified product should be able to connect "**without special effort**", meaning that these APIs are:
  - **Standardized** – built on modern computing standards such as RESTful interfaces and XML/JSON and tested in real-world settings prior to certification
  - **Transparent** – vendors must provide freely accessible, clear documentation on how to call APIs and what is returned.
  - **Pro-competitive** – vendors must not interfere with a provider's ability to use a competitor's API and connect it to their EHR or other certified technology
- **No information blocking** – all actors must not act in ways that impede data flow (with exceptions)

What are the Feds Thinking? – TEFCA

- Trusted Exchange Framework and Common Agreement (TEFCA)
  - The 21st Century Cures Act of 2016 required ONC to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."
  - Draft Trusted Exchange Framework was released by ONC on 1/5/2018 (no final framework has been released as of 3/26/2019).
  - Establishes a minimum set of requirements to enable appropriate health information exchange *among networks*.
  - Establishes principles for trusted exchange to serve as guardrails to engender trust among health information networks (HINs).

Source: ONC

How will the Trusted Exchange Framework work?



Source: ONC

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What is included (and not included) in TEFCA?

INCLUDED:

- 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.

NOT INCLUDED:

- No 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.

Source: ONC

What are the Feds thinking? – HHS HIPAA RFI

- HHS sought comments on modifying HIPAA rules to improve coordinated care. Specifically on:
  - **Promoting information sharing** for treatment and care coordination and/or case management by amending the Privacy Rule to encourage, incentivize, or require covered entities to disclose protected health information (PHI) to other covered entities.
  - Encouraging covered entities, particularly providers, to **share treatment information with parents, loved ones, and caregivers of adults facing health emergencies**, with a particular focus on the opioid crisis.
  - Implementing the HITECH Act requirement to include, in an accounting of disclosures, disclosures for treatment, payment, and health care operations (TPO) from an electronic health record (EHR) in a manner that provides helpful information to individuals, while minimizing regulatory burdens and disincentives to the adoption and use of interoperable EHRs.

NOTE: HHS received 1,337 comments in response to this RFI.

Source: Federal Register

What are the Feds thinking? – HHS HIPAA RFI (continued)

- HHS sought comments on modifying HIPAA rules to improve coordinated care. Specifically on:
  - **Eliminating or modifying the requirement for covered health care providers to make a good faith effort to obtain individuals' written acknowledgment of receipt of providers' Notice of Privacy Practices**, to reduce burden and free up resources for covered entities to devote to coordinated care without compromising transparency or an individual's awareness of his or her rights.
  - OCR therefore requests input on whether it should modify or otherwise clarify provisions of the Privacy Rule to **encourage covered entities to share PHI with non-covered entities when needed to coordinate care and provide related health care services and support** for individuals in these situations.
  - **Should health care clearinghouses be subject to the individual access requirements**, thereby requiring health care clearinghouses to provide individuals with access to their PHI in a designated record set upon request?

Source: Federal Register

What are the Feds thinking? – CMS NPRM

- On February 11, 2019, the Center for Medicare and Medicaid Services (CMS) issued a Notice of Proposed Rulemaking on improving interoperability of EHRs and patient access to their data. The comment period for this rule ends on May 3, 2019.

- In addition to the NPRM, CMS also issued two related requests for information (RFIs) on improving patient matching and approaches to interoperability in long-term, post-acute, mental health, and other ancillary care settings.

CMS NPRM – Interoperability and Patient Access

- **Highlights of proposed rules:**
  - **Patient access to data through Application Programming Interfaces (APIs):** Participating payers must create FHIR®-based APIs to make patient claims and other health information available to patients through third-party applications and developers.
  - **Health information exchange and care coordination across payers:** Payers must share patient data when they transition to a new plan.
  - **API access to published provider directory data:** Payers must make provider networks available to enrollees and prospective enrollees through API technology.
  - **Care coordination through trusted exchange networks:** CMS proposes requiring MA organizations (including MA-PD plans), Medicaid managed care plans, CHIP managed care entities, and QHP issuers in the FFEs to participate in trust networks to improve interoperability.

CMS NPRM – Interoperability and Patient Access (Continued)

- **Highlights of proposed rules:**
  - **Improving the Dual Eligible experience by increasing frequency of federal-state data exchanges:** More timely lists of Dual Eligibles from states.
  - **Public reporting and prevention of information blocking:** Publicly post which hospitals are not attesting to prevention of information blocking.
  - **Provider digital contact information:** Addition of digital contact info to the National Plan and Provider Enumeration System (NPPES)
  - **Revisions to Conditions of Participation for Hospitals and Critical Access Hospitals:** requirement for participation to send admission-discharge-transfer (ADT) notifications.
  - **Advancing interoperability in innovative models:** Grant opportunities through the Center for Medicare and Medicaid Innovation (CMMI)

What are the Feds thinking? – ONC NPRM

 **Sec. 4004 Information Blocking**	• ONC proposes seven categories of practices that would be considered reasonable and necessary that, provided certain conditions are met, would not constitute information blocking. These categories were developed based on feedback from stakeholders and consultation with appropriate federal agencies. • If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy an exception, the actions would not be treated as information blocking and the actor would not be, as applicable, subject to civil penalties or other disincentives under the law.
 **Executive Order 13813** **Promoting Healthcare Choice and Competition Across the United States**	• ONC's proposed rule would contribute to fulfilling Executive Order 13813 by furthering patient (and health care provider) access to EHI and supporting competition in health care markets through new tools to access EHI and policies to address the hoarding of EHI. • ONC's proposed rule calls on the health care industry to adopt standardized APIs, which would allow individuals to securely and easily access structured EHI using new and innovative applications for smartphones and other mobile devices. • The proposed rule would establish information blocking provisions, focusing on improving patient and health care provider access, exchange, and use of EHI.

Source: ONC

ONC NPRM – Highlights

- New Acronym Alert: EHI – Electronic Health Information
  - ONC proposed rules apply explicitly to health information in electronic form.
  - Defined as electronic protected health information that identifies the individual and is transmitted by or maintained in electronic media, that relates to the past, present, or future health or condition of an individual.
- Regulated actors:
  - Health Care Provider
  - Health IT Developer
  - Health Information Exchange
  - Health Information Network
- Vendors that have one certified product have to comply with rules for ALL of their software products (i.e., can't have one narrow solution that is certified and claim all the other pieces aren't part of the certified solution).

Source: ONC

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ONC NPRM – Information Blocking: 7 Exceptions

- Preventing harm
  - Actor has a reasonable belief that the practice of not sharing EHI will directly and substantially reduce the likelihood of harm to a patient (e.g. mental health).
- Promoting the privacy of electronic health information
  - Actor may engage in practices that protect the privacy of EHI, based on sub-exceptions focused on scenarios that recognize existing privacy laws and privacy-protective practices (**What Connecticut laws could be impacted by this exception?**)
- Promoting the security of electronic health information
  - The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI. A general prohibition is not acceptable.

Source: ONC

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ONC NPRM – Information Blocking: 7 Exceptions

- Recovering costs reasonably incurred
  - Actor may recover costs that reasonably incurred, in providing access, exchange, or use of EHI (cannot be arbitrary or discriminatory).
- Responding to requests that are infeasible
  - Actor may decline to provide access, exchange, or use of EHI if it imposes a substantial burden that is unreasonable (difficult to claim if using certified tech).
- Licensing of interoperability elements on reasonable and non-discriminatory terms
  - Technology licenses that are necessary to enable EHI access must be offered on reasonable and non-discriminatory terms.
- Maintaining and improving health IT performance
  - Health IT can be made temporarily unavailable in order to perform maintenance or improvements to the health IT, but for no longer than necessary to achieve the maintenance or improvements

Source: ONC

ONC NPRM – Consent management

- The 2015 Certification Edition contained two "**data segmentation for privacy**" (DS4P) criteria, but were never required for certification or used in any HHS programs. Since that time, more work has been done on simplifying consent protocols and making them easier to implement in an API-driven environment.
- **Consent2Share** (C2S) is an open source application for data segmentation and consent management.
- C2S enables data segmentation and consent management for disclosure of several discrete categories of sensitive health data related to conditions and treatments including: alcohol, tobacco and substance use disorders (including opioid use disorder), behavioral health, HIV/AIDS, and sexuality and reproductive health.

ONC NPRM – Consent management

- SAMHSA created a Consent Implementation Guide that describes how the Consent2Share application and associated access control solution uses the FHIR Consent resource to represent and persist patient consent for treatment, research, or disclosure.
- Note that the specification requires the use of FHIR Release 3, which is still a trial standard and not a balloted standard (all other certification requirements reference FHIR Release 2, a balloted standard).
- ONC is proposing to use this specification as a certification requirement.

Open Discussion

Consent Policy Design Group – High-Level Work Plan

Meeting Focus	Meeting Objectives
Meeting 1 – 3/26/2019 1pm – 2pm Kickoff and orientation	• Review and discuss project charter and proposed process for achieving desired outcomes • Orientation on relevant policies and procedures and semantic alignment / shared understanding of key terms
Meeting 2 – 4/9/2019 1pm – 2pm Current consent policies	• Establish understanding around current state of consent policies in Connecticut and bordering states • Consider draft language for a HIPAA TPO consent policy for recommendation to Advisory Council
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Meeting 4 – 5/7/2019 1pm – 2pm Matching use cases to consent model	• Review and discuss received input from Advisory Council or other stakeholders • Review use cases where individual consent is required by state or federal law, or areas of ambiguity
Meeting 5 – 5/21/2019 1pm – 2pm Statewide vs HIE entity consent policy framework	• Discuss the pros/cons of a statewide consent policy framework vs. HIE Entity consent policy framework to determine scope
Meeting 6 – 6/4/2019 1pm – 2pm Technical aspects of consent	• Discuss the various ways that consent could be collected and possible roles for organizations in the consent process • Establish high-level understanding of technical architecture for electronic consent management solutions • Discuss workflows that could provide individuals with information and the ability to manage preferences
Meeting 7 – 6/18/2019 1pm – 2pm Review draft consent framework recommendations	• Review and discuss strawman options • Develop draft recommendations for consent policy framework
Meeting 8 – 7/9/2019 1pm – 2pm Vote on draft recommendations	• Finalize and approve recommendations • Discuss stakeholder / general population engagement and communication process

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Background Slides

Important Acronyms

- **ADT** – Admission, Discharge and Transfer message
- **API** – Application Programming Interface
- **C2S** – Consent to Share
- **CMMI** – Center for Medicare and Medicaid Innovation
- **CMS** – Centers for Medicare and Medicaid Services
- **DS4P** – Data Segmentation for Privacy
- **EHI** – Electronic Health Information (ONC NPRM on 21st Century Cures Act)
- **EHR** – Electronic Health Record
- **HIE** – Health Information Exchange
- **HIN** – Health Information Network (TEFCA)
- **HIPAA** – Health Insurance Portability and Accountability Act of 1996
- **HITECH** – Health Information Technology for Economic and Clinical Health Act of 2009
- **HL7 FHIR®** – Health Level 7 Fast Health Interoperability Resources
- **NPRM** – Notice of Proposed Rulemaking
- **OCR** – Office of Civil Rights
- **ONC** – Office of the National Coordinator for Health Information Technology
- **PHI** – Protected Health Information (HIPAA)
- **QHIN** – Qualified Health Information Network (TEFCA)
- **RCE** – Recognized Coordinating Entity (TEFCA)
- **RFI** – Request for Information
- **SAMHSA** – Substance Abuse and Mental Health Services Administration
- **TEFCA** – Trusted Exchange Framework and Common Agreement
- **TPO** – Treatment, Payment and Operations
- **USCDI** – United States Core Data for Interoperability (21st Century Cures Act)