Consent Policy Design Group

Meeting #2
April 23, 2019

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

OHS
CONNECTICUT
Office *of* Health Strategy

Agenda

Agenda Item	Time
Welcome & introductions	1:00 pm
Public comment	1:10 pm
Review of Consent Design Group role, workplan, schedule, and desired outcomes	1:15 pm
Complete review of federal regulatory landscape; follow-up on questions from Meeting 1; address additional questions and comments from members	1:20 pm
Current state of consent policies in Connecticut: general issues and special cases (minors, SDIs, public health, mental health, etc.)	1:30 pm
High-level overview of bordering state policies	1:50 pm
Wrap-up and meeting adjournment	2:00 pm

OHS CONNECTICUT Office of Health Strategy

The Consent Policy Design Group

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

* Health IT Advisory Council Member

OHS CONNECTICUT Office of Health Strategy

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

OHS CONNECTICUT Office of Health Strategy

Consent Policy Design Group Purpose

OHS CONNECTICUT Office of Health Strategy

Consent Policy Design Group – Workplan

Meeting Focus	Meeting Objectives
Meeting 1 – 4/9/2019 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 – 4/23/2019 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 consent policy framework vs. HIE Entity consent policy framework to determine scope
Meeting 6 – 6/18/2019 1pm – 2pm Use Case B discussion	• 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 – 7/9/2019 1pm – 2pm Review draft consent framework recommendations – structure and process	• Review and discuss strawman options • 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

OHS CONNECTICUT Office of Health Strategy

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

OHS CONNECTICUT Office of Health Strategy

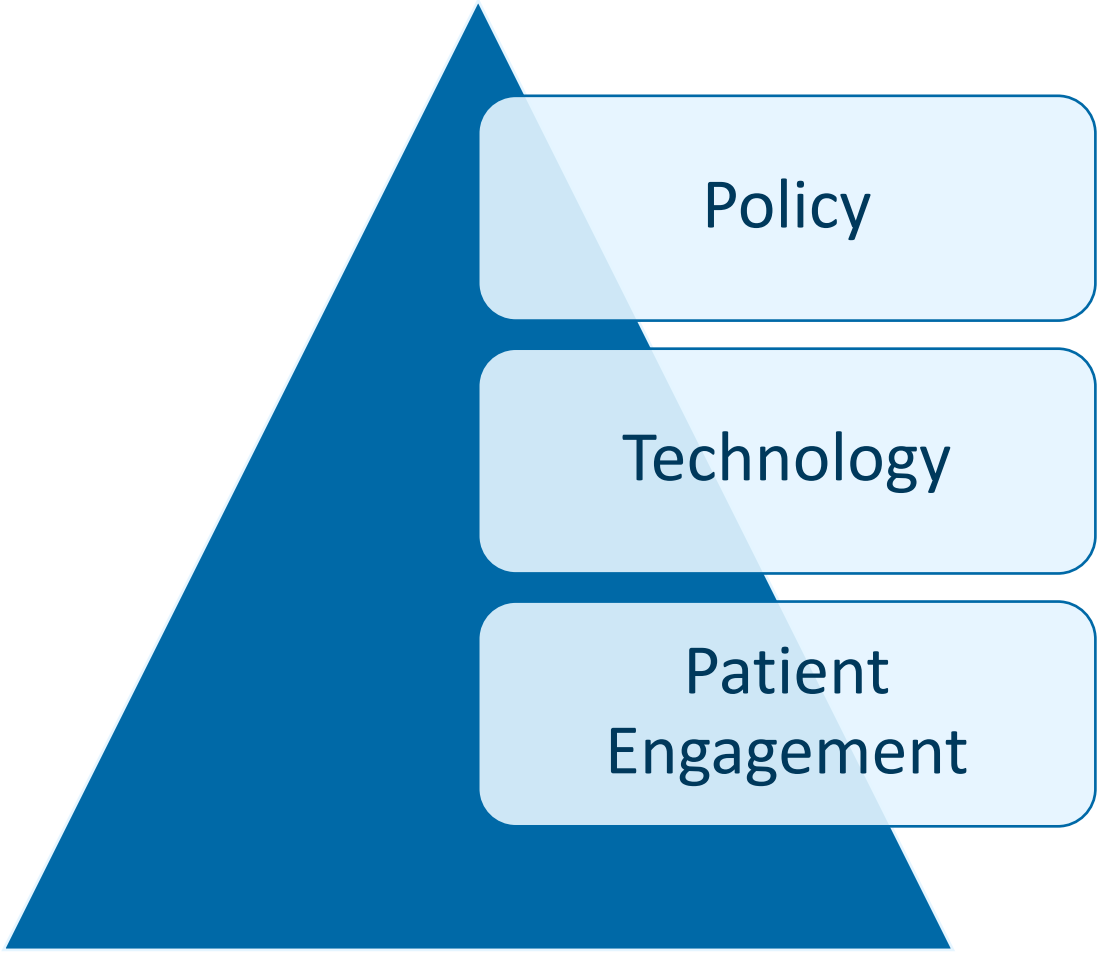
Consent Policy Design Group

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.

OHS
CONNECTICUT
Office of Health Strategy

Consent Requires Multiple Elements…



Federal Regulatory Landscape Review

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

OHS CONNECTICUT Office of Health Strategy

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)

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.

Connecticut Laws and Regulations Impacting HIE Consent Policy

Connecticut Laws and Regulations: DISCLAIMER

The following slides highlight some of the statutes and policies that may have an impact on the design of consent policies that will govern health information exchange under the new health information exchange entity. It is not intended to be an exhaustive review of all Connecticut laws that may apply to the design of consent policies for the HIE. These highlighted examples are intended to inform the design work by illustrating exceptions and other special cases that will need to be accounted for when building out the exchange and the policies that govern the exchange.

Minors – General Consent

- A minor is (with some exceptions) a person under 18 years of age.
- Consent of a minor's parent or guardian is generally required prior to the disclosure of health care information about the minor. In those circumstances when a minor may legally authorize the treatment without parental consent (outpatient mental health treatment, substance abuse treatment, or venereal disease treatment, emancipation), then only the minor can consent to the release of the information.

Resources:

- CT OLR Research Report: https://www.cga.ct.gov/2013/rpt/2013-R-0382.htm

Minors – Exceptions for Parental Consent

- Minors obtaining outpatient mental health treatment:
  - 1992 CT law enables licensed mental health professionals to provide counseling to minors (under 18 with no specific minimum age) without parental consent.
  - There are other provisions, but the relevant issue here is that if a provider is treating a minor under this statute the provider is prohibited from notifying the parent(s)/guardian of the treatment or from disclosing information about the treatment without the minor's consent. It is advised that such consent be in writing.
  - HIE will need to be able to manage this consent if any information is provided from licensed mental health providers. This doesn't apply to all minor treatment, just treatment that was requested by a minor without parental consent.

Resources:

- Overview from Social Workers Site: http://naswct.org/professional-information/links/outpatient-mental-health/
- Regulation: https://www.cga.ct.gov/current/pub/chap_368a.htm#sec_19a-14c
- Judicial Branch: https://www.jud.ct.gov/juv_infoguide/IJCP_MedicalTreatmentMinors.html#fnContent40

OHS CONNECTICUT Office of Health Strategy

Minors – Exceptions for Parental Consent

- Minors obtaining substance abuse treatment:
  - If the person seeking treatment or rehabilitation for alcohol dependence or drug dependence is a minor, the fact that the minor sought such treatment or rehabilitation or that the minor is receiving such treatment or rehabilitation, **shall not be reported or disclosed to the parents or legal guardian of the minor without the minor's consent.** The minor may give legal consent to receipt of such treatment and rehabilitation. A minor shall be personally liable for all costs and expenses for alcohol and drug dependency treatment afforded to the minor at the minor's request under section 17a-682.
  - The commissioner may use or make available to authorized persons information from patients' records for purposes of conducting scientific research, management audits, financial audits or program evaluation, provided such information shall not be utilized in a manner that discloses a patient's name or other identifying information.

Resources:

- Regulation: https://www.cga.ct.gov/current/pub/chap_319j.htm#sec_17a-688
- JUSTIA https://law.justia.com/codes/connecticut/2012/title-17a/chapter-319j/section-17a-688

OHS CONNECTICUT Office of Health Strategy

Minors – Exceptions for Parental Consent

- Minors obtaining venereal disease treatment:
  - A doctor may examine and treat a minor for venereal disease. Records of the treatment are confidential and may not be disclosed to the parent or guardian. The minor is financially responsible for the treatment, and payment may not be sought from the parent or guardian. If the minor is under 12 years of age, however, the treating physician must report it to DCF.

Resources:

- Regulation: https://www.cga.ct.gov/current/pub/chap_368e.htm#sec_19a-216
- CT Judicial Info Guide: https://www.jud.ct.gov/juv_infoguide/IJCP_MedicalTreatmentMinors.html#fnContent42

OHS CONNECTICUT Office of Health Strategy

Minors – Exceptions for Parental Consent

- Emancipated minors:
  - A minor who is at least 16 years of age may petition the court for emancipation. The effect of emancipation is to release the parent or guardian from all obligations of guardianship and allows the emancipated minor to assume the responsibilities of an adult, **including consenting to medical, dental or psychiatric care**.

Resources:

- Regulation: https://www.cga.ct.gov/current/pub/chap_815t.htm#sec_46b-150e
- CT Judicial Info Guide: https://www.jud.ct.gov/juv_infoguide/IJCP_MedicalTreatmentMinors.html#fnContent47

Minors – Consent Design Considerations

- The consent policy will need to address issues related to fully emancipated minors and for “conditionally emancipated” minors that are able to provide their own consent under certain conditions.
- This topic is of interest because it applies to general health information exchange under TPO rules.

The Commissioner's List (reportable diseases, illnesses, labs, etc.)

- A health care provider shall report each case occurring in such provider's practice, of any disease on the commissioner's list of reportable diseases, emergency illnesses and health conditions to the director of health of the town, city or borough in which such case resides and to the Department of Public Health, no later than twelve hours after such provider's recognition of the disease.

Resources:

- CT General Statute: https://www.cga.ct.gov/current/pub/chap_368e.htm#sec_19a-215

PART A: REPORTABLE DISEASES

Physicians, and other professionals are required to report using the Reportable Disease Confidential Case Report form (PD-23), other disease specific form or authorized method (see page 4 for additional information). Forms can be found on the DPH "Forms" webpage or by calling 860-509-7994. Mailed reports must be sent in envelopes marked "CONFIDENTIAL." Changes for 2019 are in **bold font** .

Category 1 Diseases: Report immediately by telephone (860-509-7994) on the day of recognition or strong suspicion of disease for those diseases marked with a telephone (☎). On evenings, weekends, and holidays call 860-509-8000. These diseases must also be reported by mail within 12 hours.

Category 2 Diseases: All other diseases not marked with a telephone must be reported by mail within 12 hours of recognition or strong suspicion of disease.

Acquired Immunodeficiency Syndrome (1,2)
Acute flaccid myelitis
☎ **Acute HIV infection**
☎ Anthrax
Babesiosis
***Borrelia miyamotoi* disease**
☎ Botulism
☎ Brucellosis
California group arbovirus infection
Campylobacteriosis
Candida auris
Carbon monoxide poisoning (3)
Chancroid
Chickenpox
Chickenpox-related death
Chikungunya
Chlamydia (*C. trachomatis*) (all sites)
☎ Cholera
Cryptosporidiosis
Cyclosporiasis
Dengue
☎ Diphtheria
Eastern equine encephalitis virus infection
Ehrlichia chaffeensis infection
Escherichia coli O157:H7 gastroenteritis
Gonorrhea
Group A Streptococcal disease, invasive (4)
Group B Streptococcal disease, invasive (4)
Haemophilus influenzae disease, invasive (4)
Hansen's disease (Leprosy)
Healthcare-associated Infections (5)
Hemolytic-uremic syndrome (6)
Hepatitis A
Hepatitis B:
- acute infection (2)
- HBsAg positive pregnant women

Hepatitis C:
- acute infection (2)
- positive rapid antibody test result

HIV-1 / HIV-2 infection in: (1)
- persons with active tuberculosis disease
- persons with a latent tuberculous infection (history or tuberculin skin test ≥5mm induration by Mantoux technique)
- persons of any age
- pregnant women

HPV: biopsy proven CIN 2, CIN 3 or AIS or their equivalent (1)
Influenza-associated death (7)
Influenza-associated hospitalization (7)
Legionellosis
Listeriosis
Lyme disease
Malaria
☎ Measles
☎ Melioidosis
☎ Meningococcal disease
Mercury poisoning
Mumps
Neonatal bacterial sepsis (8)
Neonatal herpes (≤ 60 days of age)
Occupational asthma
☎ Outbreaks:
- Foodborne (involving ≥ 2 persons)
- Institutional
- Unusual disease or illness (9)

Pertussis
☎ Plague
Pneumococcal disease, invasive (4)
☎ Poliomyelitis
Powassan virus infection
☎ Q fever
☎ Rabies
☎ Ricin poisoning
Rocky Mountain spotted fever
Rubella (including congenital)
Salmonellosis
☎ SARS-CoV
Shiga toxin-related disease (gastroenteritis)
Shigellosis
Silicosis
☎ Smallpox
St. Louis encephalitis virus infection
☎ Staphylococcal enterotoxin B pulmonary poisoning
☎ *Staphylococcus aureus* disease, reduced or resistant susceptibility to vancomycin (1)
Staphylococcus aureus methicillin-resistant disease, invasive, community acquired (4,10)
Staphylococcus epidermidis disease, reduced or resistant susceptibility to vancomycin (1)
Syphilis
Tetanus
Trichinosis
☎ Tuberculosis
☎ Tularemia
Typhoid fever
Vaccinia disease
☎ Venezuelan equine encephalitis virus infection
Vibrio infection (*parahaemolyticus, vulnificus*, other)
☎ Viral hemorrhagic fever
West Nile virus infection
☎ Yellow fever
Zika virus infection

Source: CT.gov

OHS CONNECTICUT Office *of* Health Strategy

HIE Operations

- The state agencies that participate in the Connecticut Health Information Network, subject to federal restrictions on disclosure or redisclosure of information, may disclose personally identifiable information held in agency databases to the administrator of the Connecticut Health Information Network and its subcontractors for the purposes of (1) network development and verification, and (2) data integration and aggregation to enable response to network queries.
- Such disclosure must occur in compliance with state and federal laws (e.g. HIPAA and FERPA). The network administrator and their subcontractors may not further disclose personally identifiable information.

Resources:

- CT General Statute: https://www.cga.ct.gov/current/pub/chap_368a.htm#sec_19a-25f

HIV Status

- No person who obtains confidential HIV-related information may disclose or be compelled to disclose such information, except to the following:
  - The individual/guardian
  - Someone with a release of information
  - Authorized public health officer
  - Health care provider when knowledge is necessary to provide care
  - Health care worker exposed to bodily fluids
  - 8 other exceptions
- Anyone with the disclosed information cannot further disclose.

Resources:

- CT General Statute: https://www.cga.ct.gov/current/pub/chap_368x.htm#sec_19a-583

Cancer Registry

- The Department of Public Health must maintain a tumor registry to house reports of tumors diagnosed or treated in Connecticut. Hospitals, clinical laboratories, and health care providers must report demographic, treatment, and medical information to the Registry as specified by the department.
- DPH shall be provided such access to records of any health care provider, as the department deems necessary, to perform case finding or other quality improvement audits.

Resources:

- CT General Statute: https://www.cga.ct.gov/current/pub/chap_368a.htm#sec_19a-72

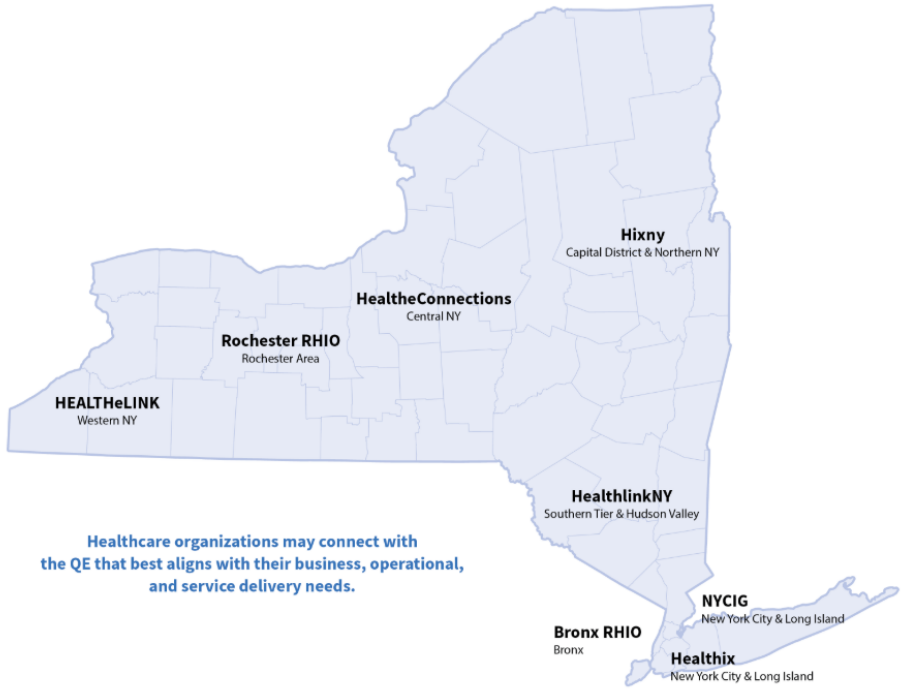
Consent in Other States

Regional State Consent Policies – Examples

State	Policy	Scope
Maine	Opt-Out	Applies to the state-designated HIE
Maryland	Opt-Out (Opt-In for some services)	Applies to state-designated HIE and all qualifying HIEs in the state
Massachusetts	Opt-In/Opt-Out	Applies to all providers and state-funded plans
New Hampshire	Opt-Out	Applies to the state-created HIE
New Jersey	Opt-Out	NJHIN is a network of networks that includes several Health Information Organizations
New York	Opt-In	Applies only to qualified entities certified by the state of New York to participate in the Statewide Health Information Network for New York (SHIN-NY)
Rhode Island	Opt-In	Applies to the state-designated HIE
Vermont	Opt-In	Applies to providers participating in VHIE and Vermont State Blueprint for Health HIEs

Statewide Health Information Network for New York (SHIN-NY)

- The New York model for consent generally fits in the "opt-in" bucket.
- Network-of-networks consisting of eight regional networks (Qualified Entities or QEs)



[Bronx RHIO]

[HealtheConnections]

[HEALTHeLINK]

[Healthix]

[Hixny]

[NY Care Information Gateway (NYCIG)]

[Rochester RHIO]

Source: NYeC

HS CONNECTICUT Office *of* Health Strategy

Statewide Health Information Network for New York (SHIN-NY)

- SHIN-NY relies on a consent-to-access rather than a consent-to-disclose model. Under a consent-to-access model, patient information is uploaded by participants to the QE without patient consent under a business associate agreement. However, the data maintained by the QE is generally not available to participants until the patient provides consent authorizing the participant to access the patient's information.
- No active consent is required for point-to-point exchange between provider with a care relationship with the patient (e.g., lab results reporting for ordered labs; Direct messaging)
- Hospitals and healthcare facilities with certified EHRs are required to participate in SHIN-NY

Statewide Health Information Network for New York (SHIN-NY)

- Privacy and Security Policies and Procedures for Qes and their Participants in New York State (revised December 2018)
  - Drives the requirements for consent and other policy requirements for Qualified Entities (QEs) participating in SHIN-NY.
  - Core consent discussion is on pp 9-19 with additional topics through p 27.
  - https://health.ny.gov/technology/regulations/shin-ny/docs/privacy_and_security_policies.pdf
- NYeC SHIN-NY Consent Whitepaper (February 2017)
  - Excellent summary of consent options that can inform our discussion
  - Useful discussion about the development of a SHIN-NY Wide Consent Model
    - The current model requires that consent be obtained by every healthcare provider who wishes to access. QEs may offer blanket consent, but there are rules for informing patients when participants in the exchange change.
    - Proposed option would create one consent form to govern all appropriate access to patient information.
  - http://www.nyehealth.org/nyec16/wp-content/uploads/2017/02/SHIN-NY_consent_white_paper_022817.pdf

Mass HIway (Massachusetts)

- Combination Opt-In/Opt-Out model
- Direct messaging (secure provider-to-provider email):
  - Mass HIway users may transmit information via HIway Direct Messaging and my implement a local opt-in and/or opt-out process that applies to the use of HIway Direct Messaging by their organization, but are not required to do so.
  - Aligns Direct with making a phone call or sending a fax.

Source: Mass HIway

Mass HIway (Massachusetts)

- HIway-sponsored Services (note that none are available yet):
  - Opt-in. HIway participants must provide each patient and/or their legal representatives with written notice of how the organization uses HIway-sponsored services.
    - Written notice (in multiple languages if required) must be provided via inclusion in a Notice of Privacy Practices, a patient handout, or a letter, email or other personal electronic communication to the patient.
    - The written notice must describe the manner and means that the patient can opt-out of HIway-sponsored services.
  - Opt-out. The Mass HIway or its designee administers a centralized opt-out system. Patients and/or their authorized designees (including the provider) may notify the Mass HIway or its designee directly if they choose to opt out.
  - Local opt-in opt-out. HIway participants may choose to implement their own local opt-in and/or opt-out process that applies to the use of HIway-sponsored Services by their organization, but are not required to do so.

Source: Mass HIway

Chesapeake Regional Information System for our Patients (CRISP – Maryland)

- Opt-Out
  - Patient informed through required additions to HIPAA Notice of Privacy Practices (NPP) for all Participating Entities.
  - NPP language must inform the patient on how to opt out of CRISP.
  - Opt-out forms must be available to patients receiving care from Participating Entities. Also available online and by calling CRISP.
  - Low opt-out rate (<0.5%).
- Opt-In for some services
  - Research requires consent in most instances
  - Services covered by 42 CFR Part 2 (substance abuse treatment), some ancillary services.

HIE Consent Form Examples

- Camden HIE (NJ): https://www.camdenhealth.org/wp-content/uploads/2017/12/CAMDEN-HIE-OPT-OUT.pdf
- CRISP (MD, DC): https://crisphealth.org/wp-content/uploads/2019/02/Optout-Form-English-2019.pdf
- SHIN-NY (NY): https://health.ny.gov/technology/regulations/shin-ny/docs/privacy_and_security_policies.pdf (appendix)
- Southeast Nebraska Behavioral Health Information Network: https://healthit.ahrq.gov/sites/default/files/docs/behavioral-health-consent-022713.pdf
- St. Joseph Health (CA): http://www.stjhs.org/documents/HIE/48795330_SJH_HIE_OptInForm.pdf
- CurrentCare (RI): http://www.currentcareri.com/Portals/0/Uploads/Documents/CC_and_CC4Me_Dual_Enrollment_Form-031017F.pdf
  - Online enrollment: https://enroll.currentcareri.org/

OHS CONNECTICUT Office of Health Strategy

Open Discussion

Consent Policy Design Group – Workplan

Meeting Focus	Meeting Objectives
✓ **Meeting 1 – 4/9/2019 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 – 4/23/2019 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 consent policy framework vs. HIE Entity consent policy framework to determine scope
Meeting 6 – 6/18/2019 1pm – 2pm Use Case B discussion	• 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 – 7/9/2019 1pm – 2pm Review draft consent framework recommendations – structure and process	• Review and discuss strawman options • 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

OHS CONNECTICUT Office of Health Strategy

Background Slides

Important Acronyms (Red Font Indicates New Entry)

- **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
- **FERPA** – Family Educational Rights and Privacy Act
- **HIE** – Health Information Exchange
- **HIN** – Health Information Network (TEFCA)
- **HIO** – Health Information Organization
- **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
- **NPP** – HIPAA Notice of Privacy Practices
- **NPRM** – Notice of Proposed Rulemaking
- **OCR** – Office of Civil Rights
- **ONC** – Office of the National Coordinator for Health Information Technology
- **QE** – Qualified Entity (NY)
- **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
- **SHIN-NY** – Statewide Health Information Network for New York
- **TEFCA** – Trusted Exchange Framework and Common Agreement
- **TPO** – Treatment, Payment and Operations
- **USCDI** – United States Core Data for Interoperability (21st Century Cures Act)

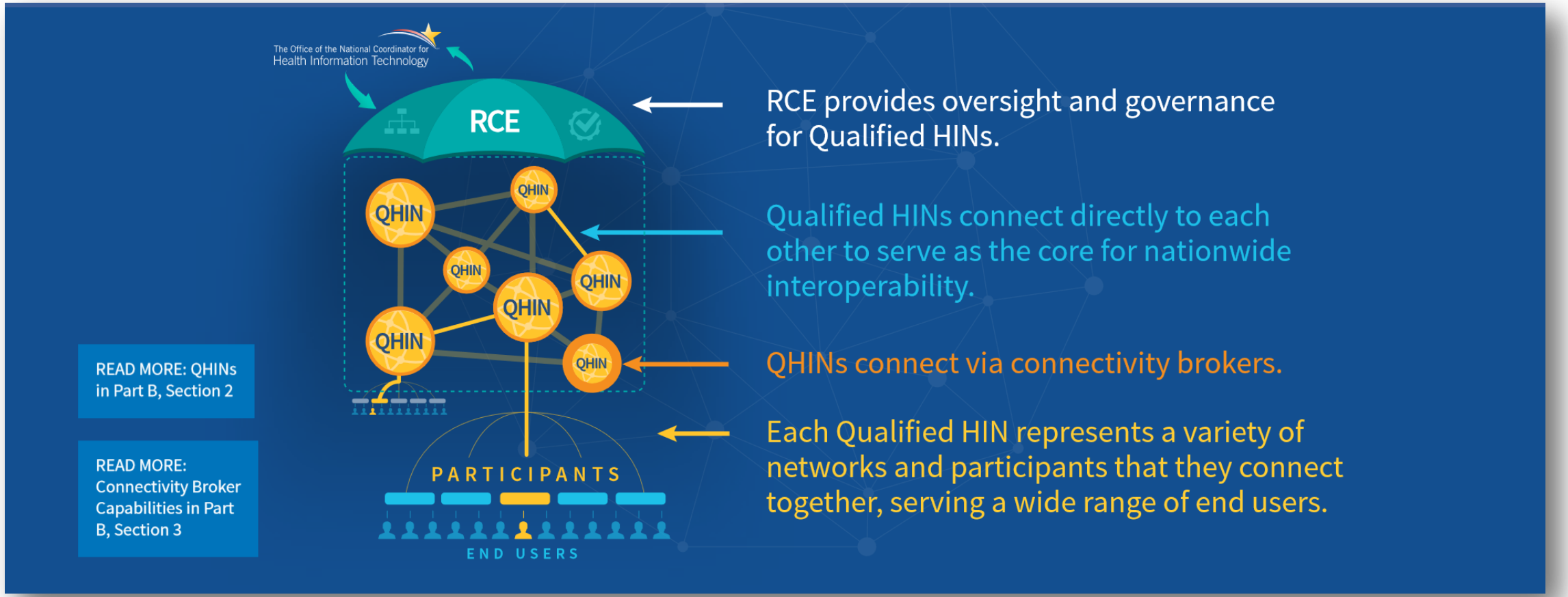
What are the Feds thinking? – TEFCA

- 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

OHS CONNECTICUT Office of Health Strategy

How will the Trusted Exchange Framework work?



Source: ONC

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

OHS CONNECTICUT Office *of* Health Strategy

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

OHS CONNECTICUT Office of Health Strategy

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