Agenda

- Welcome and Introductions
- NY HISPC Project Purpose
- Review of Findings from Meeting #1 and Charge for Meeting #2
- Facilitated Discussion: Principles of a New Policy Framework for Consumer Consent
- Next Steps
NY HISPC Part 1 Findings: Variations in HIE

- **Role of Regional Health Information Organizations (RHIOs):** RHIOs can play an important role in health information exchange by acting as a trusted broker to establish and maintain privacy and security policies.

- **Human Judgment in Information Exchange:** Current decisions regarding what health information to disclose, when and to whom, rely heavily on human judgment and personal interaction.

- **From One-to-One to Many-to-Many:** Moving to the broad transfer of information to many persons or entities will require many layers of sophisticated permissions and controls to replicate the current practice.

- **Appropriate Scope of Disclosure:** There is a need to define more clearly who is allowed to see what information and to understand how to accommodate appropriate access in an electronic environment.

- **Use of Administrative Data for Clinical Purposes:** Ideally, data should be gathered at the point of care for multi-purpose clinical use; the utility of billing data for clinical purposes should be reviewed.

- **Sensitive Data:** Variation in legal standards for different categories of highly sensitive data must be addressed in a way that earns the public’s trust.

- **Informed Patient Consent and Authorization:** Transparent and informed patient consent that is tracked and monitored is a key requirement to health information exchange.
## NY HISPC Part 1: Priority Solution Areas

<table>
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<tr>
<th>Priority Solution Area</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Patient Engagement</strong></td>
<td>Support the right of patients to expeditiously access their own health information, and to make choices about the collection, storage, use and disclosure of their data. Engage people in taking a more informed and active role in their own health care.</td>
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<tr>
<td><strong>Consent (NY HISPC Part 2 Focus)</strong></td>
<td>Ensure that patients are able to make meaningful consent decisions about the disclosure of their healthcare information, and that custodians of healthcare information comply with patient consent mandates under state and federal law.</td>
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<tr>
<td><strong>Security/Access/Use</strong></td>
<td>Establish a common set of interoperable policies and technical requirements determining: data access and use; authentication; auditing, compliance and software and data security.</td>
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<tr>
<td><strong>Patient Identification</strong></td>
<td>Provide for a reliable approach to correctly match patients with their health information ensuring providers have the right record(s) for the right patient at the point of care.</td>
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NY HISPC Part 1
Implementation Framework/Approach

**Priority Solutions Areas**

- **Patient Engagement**
  - Consent
  - Security/Access/Use
  - Patient Identification

**Leadership Entity**
- Identify or establish an independent, statewide, public-private group to:
  - Convene stakeholders
  - Align HIE policies
  - Identify best practices
  - Publish recommendations
  - Provide technical, business practice and policy guidance

**Accreditation Process**
- Establish a private sector accreditation process for RHIOs that ensures a minimum level of privacy and security practices across the state.
- Evaluate whether accreditation would qualify for certain benefits such as eligibility for state funding, access to Medicaid data, etc.

**Clarification of Laws**
- Establish a shared interpretation of relevant state and federal regulations that impact HIE.

**New Laws**
- Create new law where necessary to govern the electronic exchange of health information.
RHIOs have responsibility for ensuring privacy and security of information collected and exchanged:

- Use and disclosure policies
- Authentication of identity
- Authorization for access
- Consumer and provider identification
- Transmission security
- Data integrity
- Administrative and physical security
NY HISPC Part 2: Project Purpose

- To recommend and implement a standardized consent process for RHIOs in NYS
  - Provide clarity on and ensure consistency in consent process
  - Advance health information exchange
  - Develop legal/regulatory framework to define and give RHIOs standing to address patient consent on behalf of physicians, providers and New Yorkers
  - Engage consumers as active participants in their health care
  - Enable incentives and protections to encourage participation
Review of Findings from Meeting #1 and Charge for Meeting #2
Stakeholder Meeting #1
Meeting Goal: Identify the Problem

- Establish a common understanding of key issues relating to consumer consent in a health information exchange environment as well as NY HISPC project goals.

- Identify specific issues that need to be addressed when formulating new policy governing consumer consent in the RHIO context.
## Stakeholder Meeting #1
### Findings

### Observations from First Stakeholder Meeting
- Definitional Issues
- Uses of information
- Exchange of sensitive information
- Standardized, meaningful consent process
- Adoption/compliance and transparency
- Consumer engagement

### Key Questions for RHIO Consent Rules
- **Activities**: What are the activities with respect to health information exchange we are seeking to govern and support? How do we define a RHIO?
- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent?
  - Uses of information
  - Sensitive information
  - Where and at what point consent is obtained
  - Standardized consent process
  - Durability and revocability
  - Consumer engagement
  - Audit and transparency
- **Benefits/Penalties**: What are the consequences, including benefits and penalties, of meeting the obligations defined above?
- **Adoption/Compliance**: How and by whom will compliance be enforced?
Today’s Format

- Panel Moderator
  - Tom Check

- Panelists
  - John Blair, THINC RHIO
  - Pat Hale, ARCHIE
  - Ted Kremer, Greater Rochester
  - Barbara Radin, Bronx RHIO
  - Ben Stein, LIPIX

- Active Feedback and Discussion
Stakeholder Meeting #3 and Follow Up

Meeting # 3 (October 24; NYC)

- Review of today’s findings
- Facilitated Discussion
  - Benefits/Penalties of meeting/not meeting obligations
  - Adoption/Compliance

Post-Meeting Follow Up

- DOH will post a white paper for public comment
- White paper will summarize findings from meetings and make policy recommendations
Why New Consent Rules for RHIOs?
Why New Consent Rules for RHIOs in New York?

- Fragmented State legal and regulatory framework on consumer consent
- Gaps in legal/regulatory guidance result in diverse interpretations and implementation of consumer consent policies across RHIOs
- Diverse approaches are a barrier to interoperability
- Existing NYS laws apply to payors and providers, not entities such as RHIOs. Given central role of RHIOs in HIE, creating a common legal framework will advance HIE to improve quality and lower costs
Why New Consent Rules for RHIOs in New York?

- RHIOs participate in activities beyond one-to-one health information exchanges
  - One-to-one health information exchange generally relies on the consumer to provide the connection – e.g. results delivery
  - Community-wide information exchange permits information to be shared among providers without the consumer’s direct involvement or knowledge
- Consumer needs to understand this paradigm shift to give meaningful consent
Facilitated Discussion: Principles of New Policy Framework for Consumer Consent
New Policy Framework for RHIO Consent Rules

Mechanism for New Policy Framework

- Legislation
- Regulation
- Contracts
- Accreditation

Obligations
Adhere to standardized consent policies regarding uses of information, exchange of sensitive information, consumer engagement, etc.

Benefits/Penalties
- State funds (e.g. HEAL)
- Medicaid data
- Safe harbor protections
- Operational consistency and efficiencies
- Regulatory enforcement

ADOPTION / COMPLIANCE
Key Policy Questions for Today

- **Activities**: What are the activities with respect to health information exchange we are seeking to govern and support? How do we define a RHIO?

- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent?
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Assumptions: Applicability of a New Policy Framework for Consent

- Assume consent discussion applies to RHIOs that comply with State definition
- Designation as RHIO brings benefits (e.g. HEAL funding, Medicaid data, accreditation, etc.) but also obligations
- Consistency across RHIOs is required to promote State goals
Panel: Defining a RHIO for the Purpose of Consent
Key Policy Questions for RHIO Consent Rules

- **Activities**: What are the activities with respect to health information exchange we are seeking to govern and support? How do we define a RHIO?
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What Activities Do We Want to Support and Govern: Defining RHIOs for the Purposes of Consent

Community-wide Health Information Exchange

Consumer Access

One-to-One Exchange

HISPC PROJECT FOCUS
Six Critical Components of the RHIO Definition

- **Nature of participants**: Multi-stakeholder
- **Governance**: Transparent, inclusive decision making process
- **Purpose of exchange/Mission**: Improve quality, safety, efficiency of care
- **Type of information exchanged**: Clinical data
- **How information is exchanged**: Protocols, standards and services
- **Scope of services**: Security, authentication, authorization, access, and auditing policies
RHIOs enable development of technology architecture supported by a statewide collaboration process requiring implementation of:

- Common HIE Protocols
- CORE HIE Services
- Common Standards
RHIO Definition: How Information is Exchanged

**Definition of Issue**
Define RHIO’s role in supporting development and implementation of protocols, standards, and services required for SHIN-NY

**Considerations**
- What are the criteria and who has the authority to ensure compliance with organizational and technical requirements?
- What are the criteria to determine what exchanges fall outside the RHIO definition? E.g. One-to-one exchanges implemented independently of RHIOs
  - □ Hospital look up
  - □ Results delivery

**Recommendations**
Facilitated Discussion: Core Obligations of a RHIO with Respect to Consumer Consent Policies
Key Policy Questions for RHIO Consent Rules

- **Activities**: What are the activities with respect to health information exchange we are seeking to govern and support? How do we define a RHIO?

- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent?
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Obligations of Participation

- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent policies?

  - Uses of information
    - Sensitive information
    - Where and at what point consent is obtained
    - Standardized consent process
    - Durability and revocability
    - Consumer engagement
    - Audit and transparency
Core Issues Regarding Uses of Information

- Treatment
- Provider-based quality improvement
- Public health

- Payment
- Payer-based quality improvement

- Research
- Marketing
- Pay for performance
- Other

Level 1 Uses (Identifiable data)
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<td>Should different uses of information require different standards of consent?</td>
<td>Consumers ultimately have the right to consent to any kind of use</td>
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<td>Should use of information that could be unexpected require higher level of consent?</td>
<td>Some uses may be more acceptable to consumers than others</td>
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<td>Should use of information for research and marketing purposes require a higher level of consent than use of information for treatment purposes?</td>
<td>Multiple standards of consent can be tailored to build patient trust</td>
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<td>What, if any, standards should apply for de-identified data uses?</td>
<td>However, multiple standards will be more burdensome to implement</td>
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Obligations of Participation

**Obligations:** What are the core obligations of a RHIO with respect to consumer consent policies?

- Uses of information
- Sensitive information
- Where and at what point consent is obtained
- Standardized consent process
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- Audit and transparency
To what extent should the consumer control exchange of sensitive health information?

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| New York state law requires specific consent for various types of sensitive health information. There may be types of information beyond these legal requirements that carry a higher level of sensitivity. Various options exist for consumers to control exchange of sensitive information: | - Excluding sensitive health information can compromise quality of care  
- Excluding sensitive health information can create financial and operational burdens in health information exchange  
- Consumers may want to control access to sensitive health information that may lead to discrimination or embarrassment |                 |
| • Option 1: Consumer ability to restrict provider participation in information exchange  
• Option 2: Consumer ability to restrict discrete data elements in information exchange  
• Option 3: Consumer given a choice of not participating in exchange (all in or all out) |                                                                                                                                             |                 |

NYS Office of Health Information Technology Transformation
Obligations of Participation

- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent policies?
  - Uses of information
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  - Where and at what point consent is obtained
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Where and at what point should consent be obtained?

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<td>Prior to accessing patient information, should consent be obtained at the clinician, facility or RHIO level?</td>
<td>Multiple consents require more resources</td>
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<td>Should consent obtained by one RHIO participant suffice for all RHIO participants?</td>
<td>If one consent suffices, what happens when membership changes?</td>
<td></td>
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<tr>
<td>Should consumer consent be obtained prior to loading data? Prior to provider accessing information post-upload?</td>
<td>Providers have direct relationship with consumer, but providers are already over-burdened</td>
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<td>RHIOs apply different models to data upload, requiring variations in the point at which consent is obtained</td>
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Obligations of Participation

- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent policies?
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  - Where and at what point consent is obtained
  - **Standardized consent process**
    - Durability and revocability
    - Consumer engagement
    - Audit and transparency
### Definition of Issue
Currently, some RHIOs defer to providers to develop consent mechanisms. Others develop standardized forms for participants. Should a standardized consent form be used to promote consistency across RHIOs and participants?

### Considerations
- Standardized consent form provides consistency but reduces RHIO participant flexibility
- If RHIO participants rely on consent forms obtained by others, standardized form gives greater comfort
- Potential information on form could include:
  - Permitted uses
  - Name of RHIO participants
  - Consumer right to limit access to information
  - Consumer right to revoke consent

### Recommendations
Obligations of Participation

Obligations: What are the core obligations of a RHIO with respect to consumer consent policies?
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How durable is consumer consent? Is it revocable?

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<td>How long should consumer consent last?</td>
<td>As RHIO membership and functions change over time, consumers may change their minds about participation.</td>
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<tr>
<td>Are there triggers that require consent to be re-affirmed and if so, what are they?</td>
<td>Changes in consumer health status also may prompt changes in desire to participate.</td>
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<td>How can a consumer revoke consent?</td>
<td>Obtaining consumer consent is time and labor-intensive for RHIO participants (providers).</td>
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<td>What happens to consumer information once consent is revoked?</td>
<td>Moving individuals in and out of RHIO is labor intensive to RHIO and members and can disrupt consumer care.</td>
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Obligations of Participation

- **Obligations**: What are the core obligations of a RHIO with respect to consumer consent policies?
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**Consumer engagement**

- Audit and transparency
What are the parameters of meaningful and informed consent?

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<td>For consent to be meaningful and informed, significant consideration needs to be given to the:</td>
<td>Establish minimum standards for RHIO consent policies that requires them to be specific enough to be meaningful but broad enough to be adapted for multiple audiences</td>
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<tr>
<td>■ Process for educating consumers about how, when and by whom their personal health information can be disclosed and used?</td>
<td>■ Health literacy issues create challenges, especially multi-lingual and other special populations</td>
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Obligations of Participation

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To what extent should RHIOs conduct audits? How should a breach of consent policies be handled?

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<td>How and how often should RHIOs monitor compliance with consent policies?</td>
<td>- Audits provide assurances to RHIOs and participants that policies are effective</td>
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<td>What is the RHIO and participant’s responsibility after a breach occurs?</td>
<td>- Disclosure of breaches to consumer may raise issues of liability</td>
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<td></td>
<td>- Unclear what remedies would be available to consumer, RHIO and participants in the event of breach</td>
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Next Steps
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