

New York Health Information Security and Privacy Collaboration (NY HISPC)

October 1, 2007

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

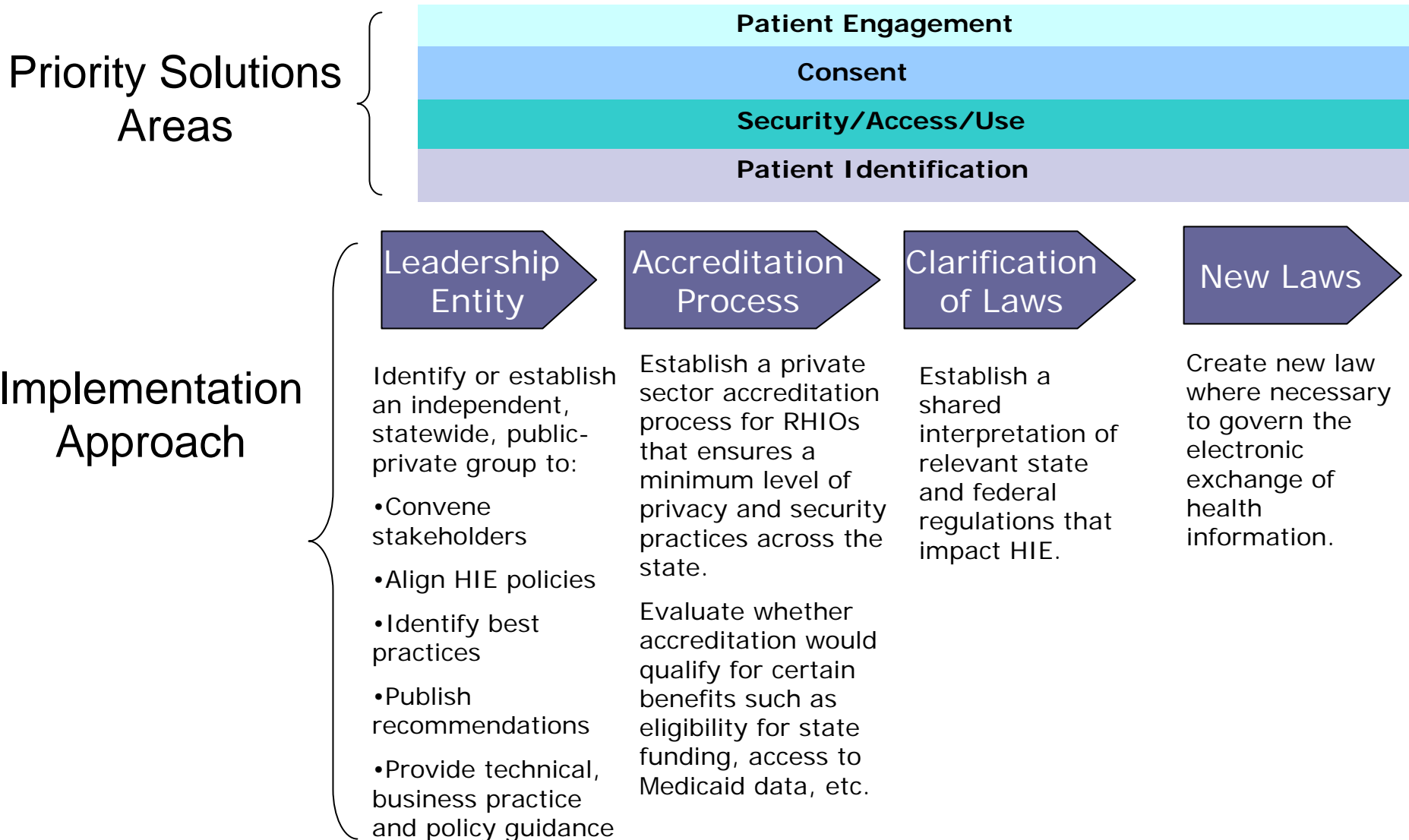
- **Role of Regional Health Information Organizations (RHIOs):** RHIOs can play an important role in health information exchange by acting as a trusted broker to establish and maintain privacy and security policies.
- **Human Judgment in Information Exchange:** Current decisions regarding what health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

Patient Engagement	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.
Consent <i>(NY HISPC Part 2 Focus)</i>	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.
Security/ Access/ Use	Establish a common set of interoperable policies and technical requirements determining: data access and use; authentication; auditing, compliance and software and data security.
Patient Identification	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.

NY HISPC Part 1

Implementation Framework/Approach



NY HISPC Part 2: Project Focus

- 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



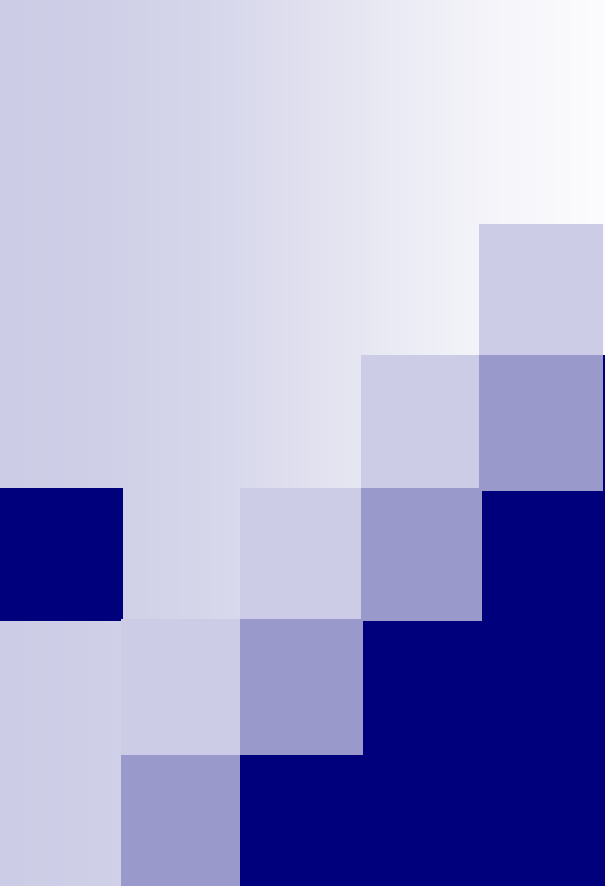
Why New Consent Rules for RHIOs?

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

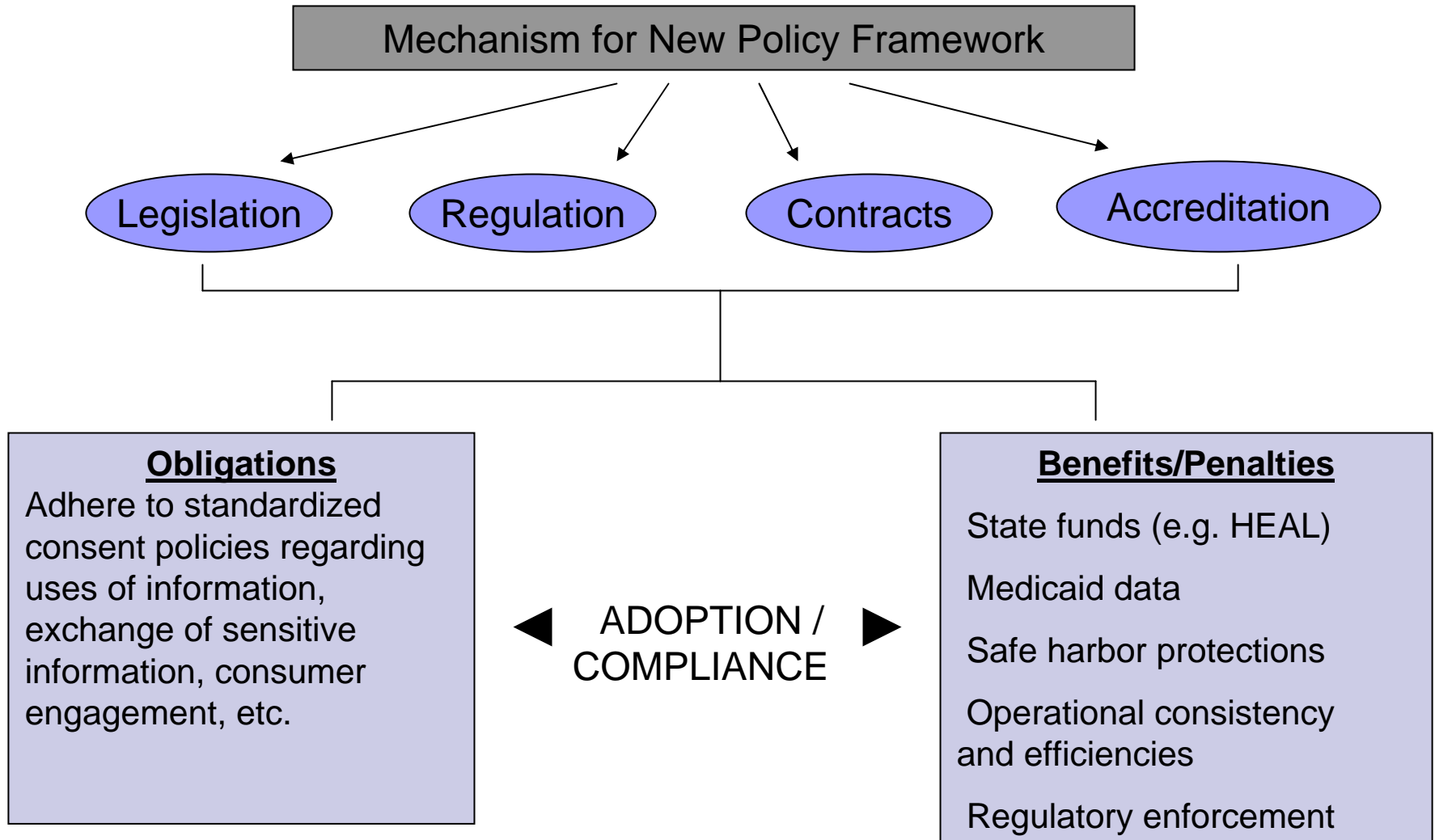
Why New Consent Rules for RHIOs in New York?

- 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



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



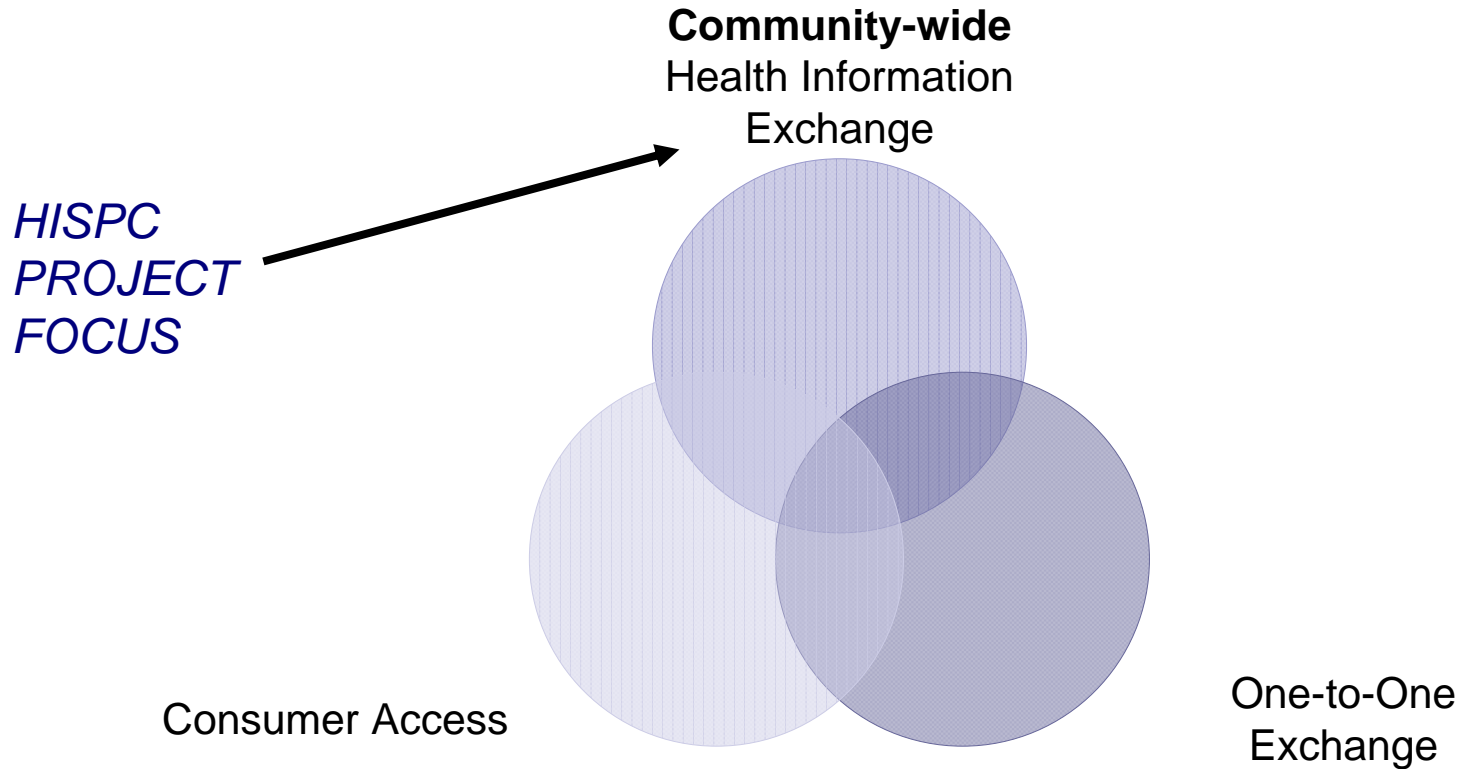
Panel: Defining a RHIO for the Purpose of Consent

Key Policy Questions for RHIO Consent Rules

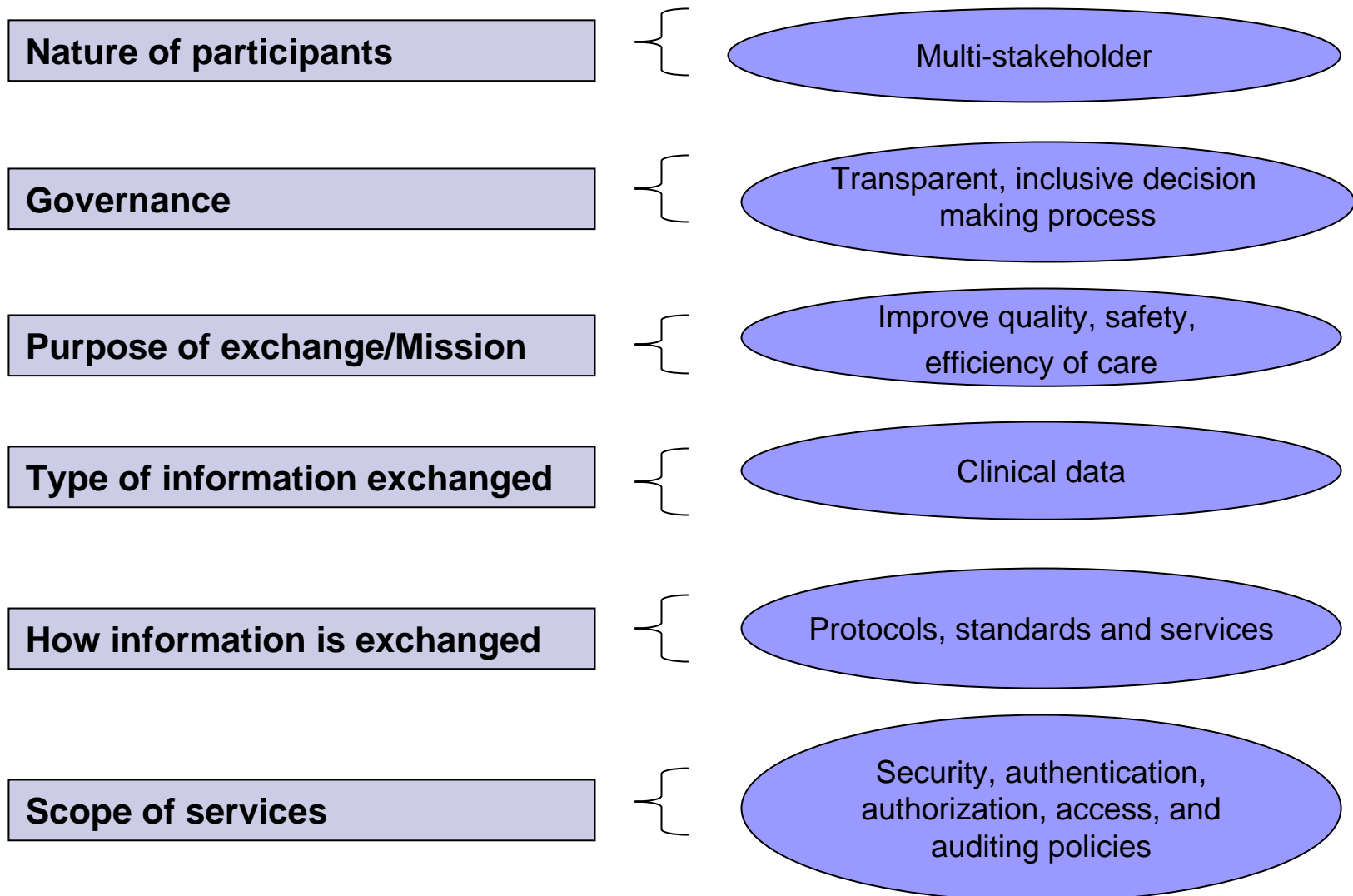


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What Activities Do We Want to Support and Govern: Defining RHIOs for the Purposes of Consent



Six Critical Components of the RHIO Definition



HEAL NY Phase 5 Framework: How Information is Exchanged

- 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



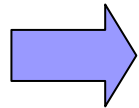
Facilitated Discussion: Core Obligations of a RHIO with Respect to Consumer Consent Policies

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?
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Obligations of Participation

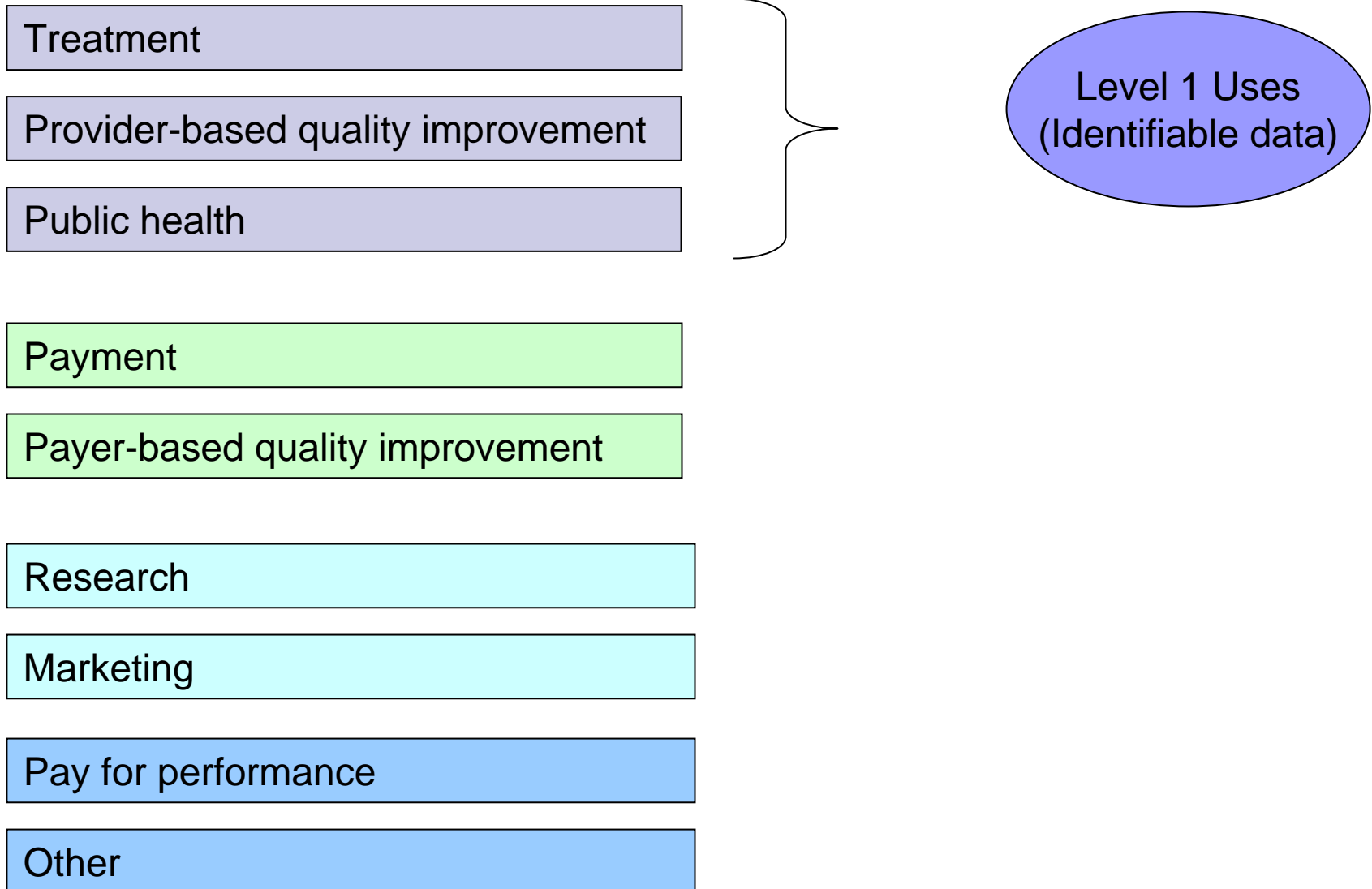
- Obligations: What are the core obligations of a RHIO with respect to consumer consent policies?



Uses of information

- Sensitive information
- Where and at what point consent is obtained
- Standardized consent process
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Core Issues Regarding Uses of Information



Should the consent process vary according to use of information?

Definition of Issue

Should different uses of information require different standards of consent?

Should use of information that could be unexpected require higher level of consent?

Should use of information for research and marketing purposes require a higher level of consent than use of information for treatment purposes?

What, if any, standards should apply for de-identified data uses?

Considerations

- Consumers ultimately have the right to consent to any kind of use
- Some uses may be more acceptable to consumers than others
- Multiple standards of consent can be tailored to build patient trust
- However, multiple standards will be more burdensome to implement

Recommendations

Obligations of Participation

- Obligations: What are the core obligations of a RHIO with respect to consumer consent policies?
 - Uses of information
 - ➔ Sensitive information
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To what extent should the consumer control exchange of sensitive health information?

Definition of Issue

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:

- 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)

Considerations

- 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

Recommendations

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 should consent be obtained?

Definition of Issue

Prior to accessing patient information, should consent be obtained at the clinician, facility or RHIO level?

Should consent obtained by one RHIO participant suffice for all RHIO participants?

Should consumer consent be obtained prior to loading data? Prior to provider accessing information post-upload?

Considerations

- Multiple consents require more resources
- If one consent suffices, what happens when membership changes?
- Providers have direct relationship with consumer, but providers are already over-burdened
- RHIOs apply different models to data upload, requiring variations in the point at which consent is obtained

Recommendations

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
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What needs to be explicitly referenced in a standardized consent form?

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?

Definition of Issue

- How long should consumer consent last?
- Are there triggers that require consent to be re-affirmed and if so, what are they?
- How can a consumer revoke consent?
- What happens to consumer information once consent is revoked?

Considerations

- As RHIO membership and functions change over time, consumers may change their minds about participation.
- Changes in consumer health status also may prompt changes in desire to participate.
- Obtaining consumer consent is time and labor-intensive for RHIO participants (providers).
- Moving individuals in and out of RHIO is labor intensive to RHIO and members and can disrupt consumer care.

Recommendations

Obligations of Participation

- Obligations: What are the core obligations of a RHIO with respect to consumer consent policies?
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What are the parameters of meaningful and informed consent?

Definition of Issue

For consent to be meaningful and informed, significant consideration needs to be given to the:

- Process for educating consumers about how, when and by whom their personal health information can be disclosed and used?

Considerations

- 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
- Health literacy issues create challenges, especially multi-lingual and other special populations

Recommendations

Obligations of Participation

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

Definition of Issue

How and how often should RHIOs monitor compliance with consent policies?

What is the RHIO and participant's responsibility after a breach occurs?

Considerations

- Audits provide assurances to RHIOs and participants that policies are effective
- Disclosure of breaches to consumer may raise issues of liability
- Unclear what remedies would be available to consumer, RHIO and participants in the event of breach

Recommendations



Next Steps

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