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

October 24, 2007

Agenda

- Welcome and Introductions
- Meeting Purpose and Goals
- Review of Findings from Meetings #1 and #2
- Facilitated Discussion
- Next Steps

NY HISPC Part 2: Project Focus

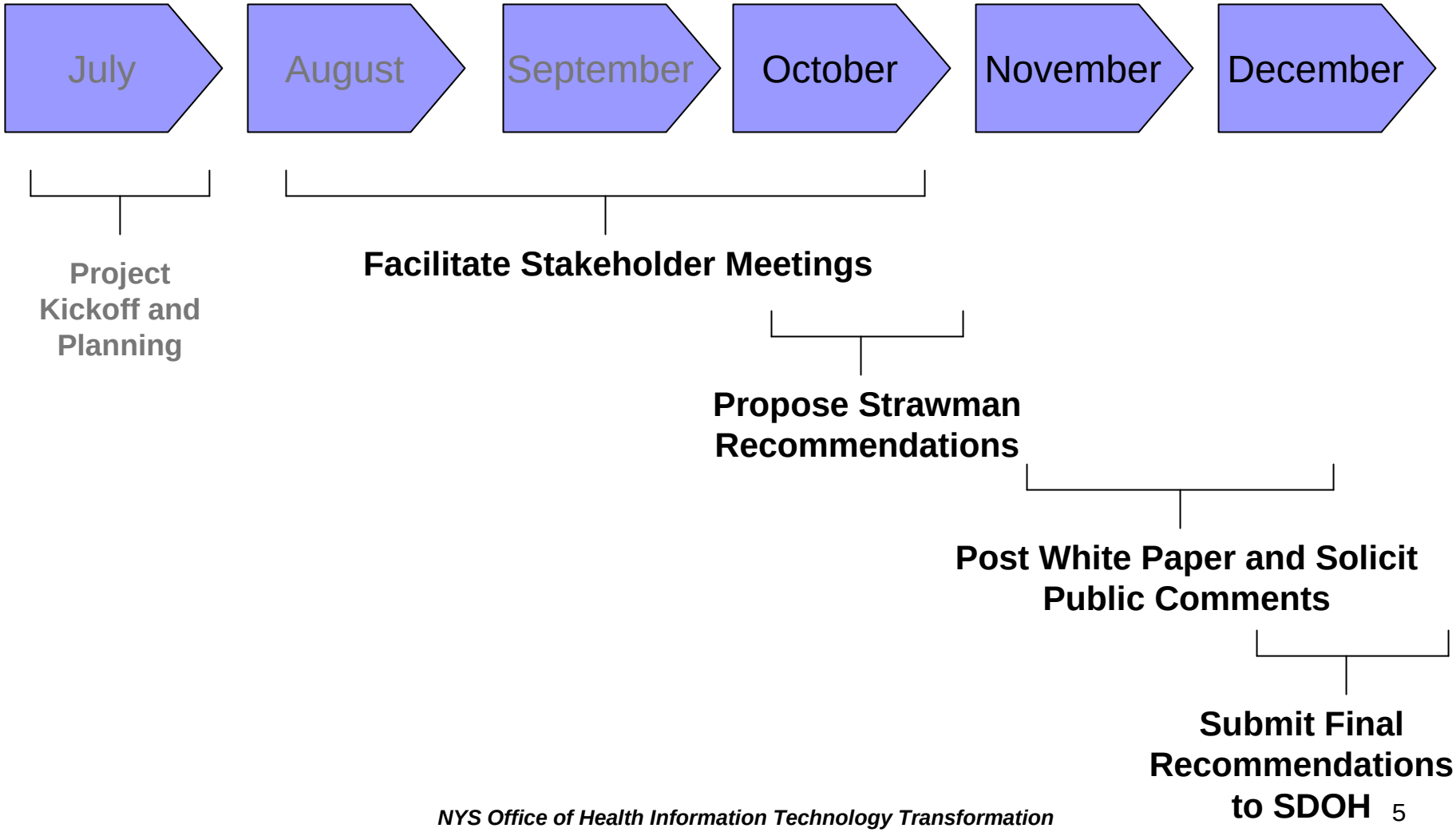
- RHIOs have responsibility for ensuring privacy and security of information collected and exchanged
  - **Use and disclosure policies** ←
  - Authentication of identity
  - Authorization for access
  - Consumer and provider identification
  - Transmission security
  - Data integrity
  - Administrative and physical security

NY HISPC Part 2: Project Purpose

- Advance health information exchange through the development and implementation of a standardized consent process for RHIOs in NYS
  - Ensure that consumer consent is informed and knowing
  - Provide clarity on and ensure consistency in consent process
  - Give RHIOs standing to address patient consent on behalf of physicians, providers and New Yorkers
  - Enable incentives and protections to encourage participation

NY HISPC Part 2

Project Timeline and Process Steps



Today's Purpose and Format

- Purpose
  - Confirmation of findings from first two meetings
  - React to "strawman" proposal
  - Affirm consensus where applicable
  - Discuss issues that need further exploration
- Format
  - Review of meeting #1 and #2 findings
  - Facilitated discussion

Review of Findings from Meeting #1 and #2

Stakeholder Meeting #1
Findings

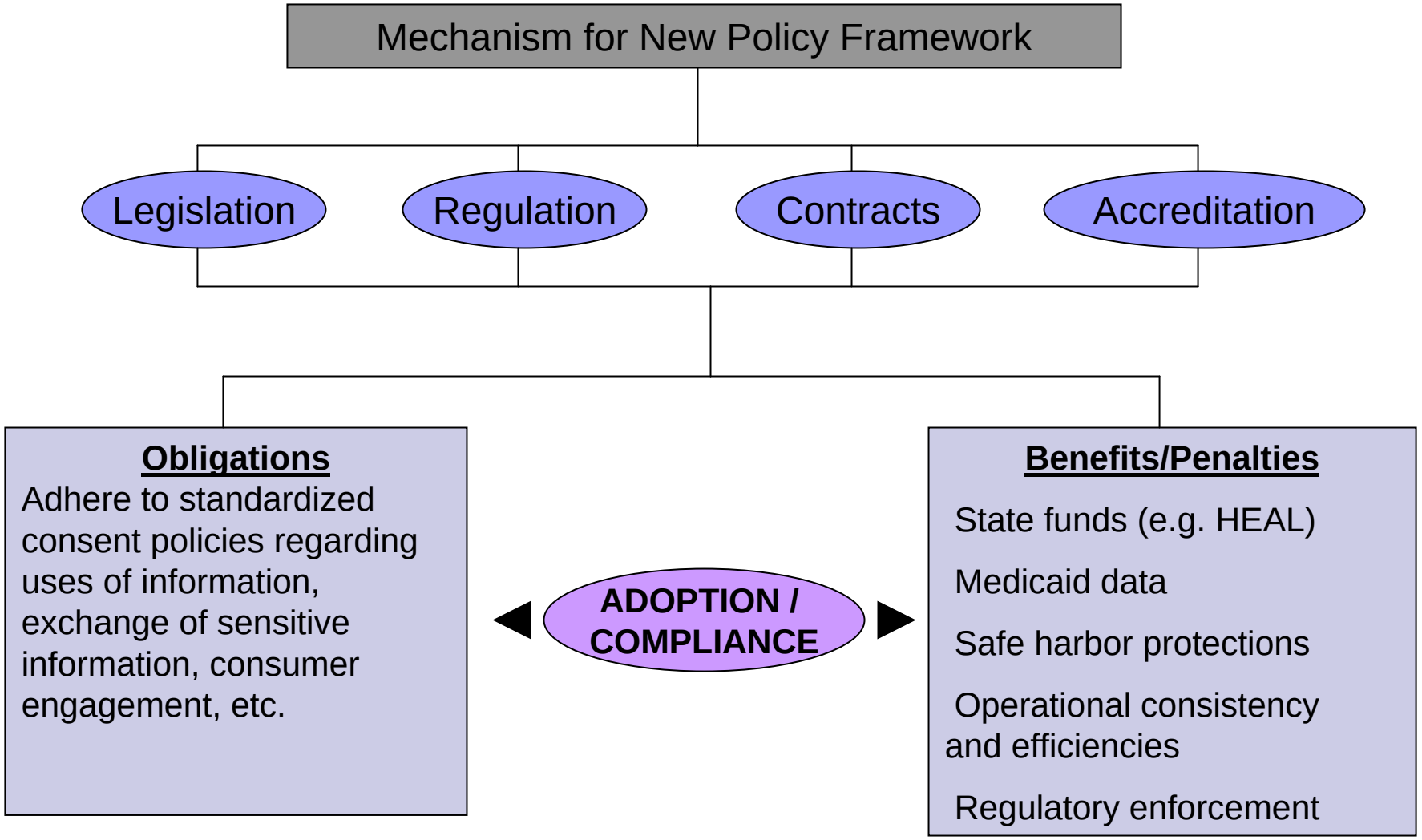
Observations from First Stakeholder Meeting

- Definitional Issues
- Uses of information
- Exchange of sensitive information
- Standardized, meaningful consent process
- Adoption/compliance and transparency
- Consumer engagement

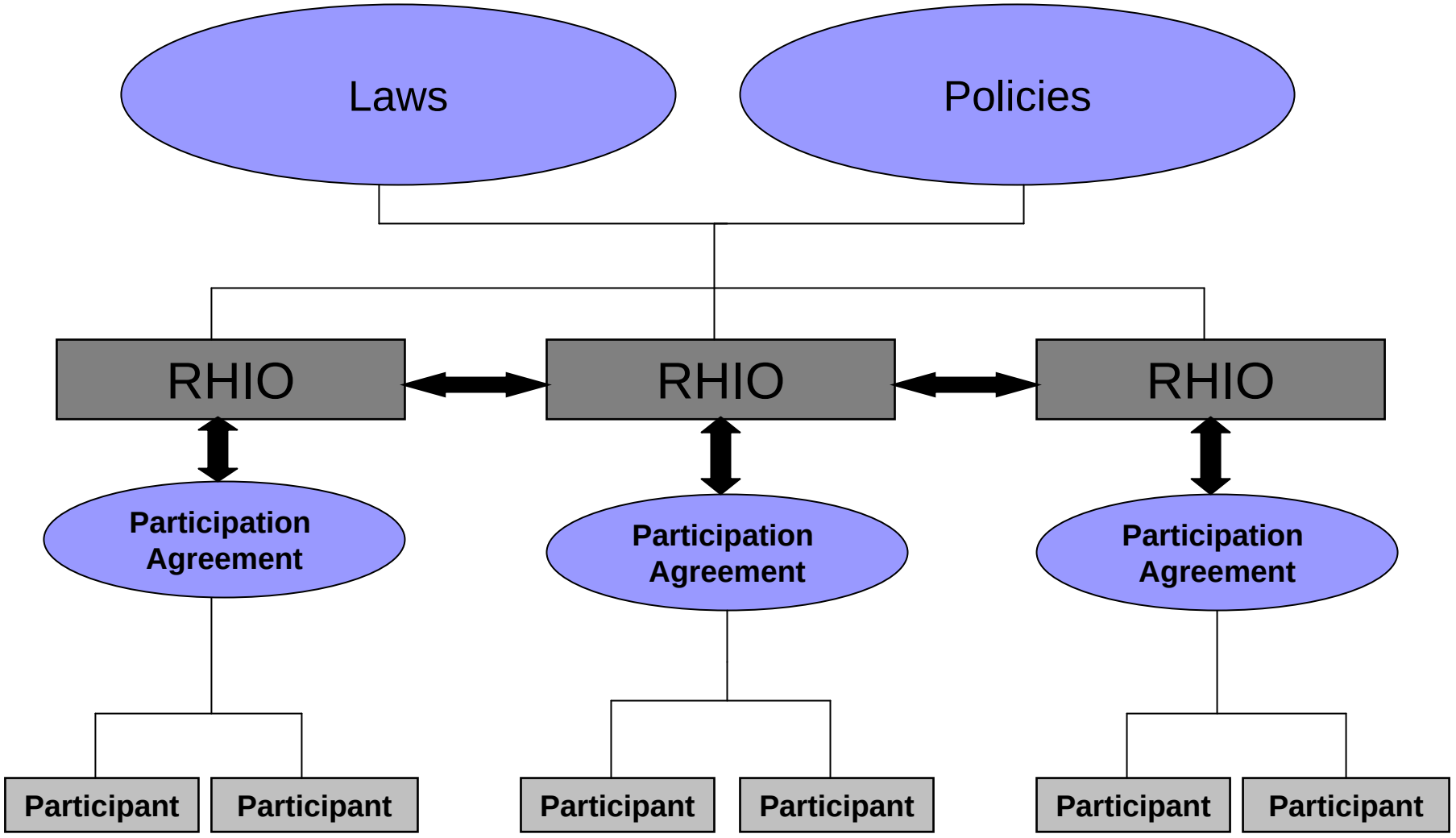
Key Questions for RHIO Consent Rules

- 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
  - Where and by whom consent is obtained
  - Provider participation and sensitive information
  - 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?

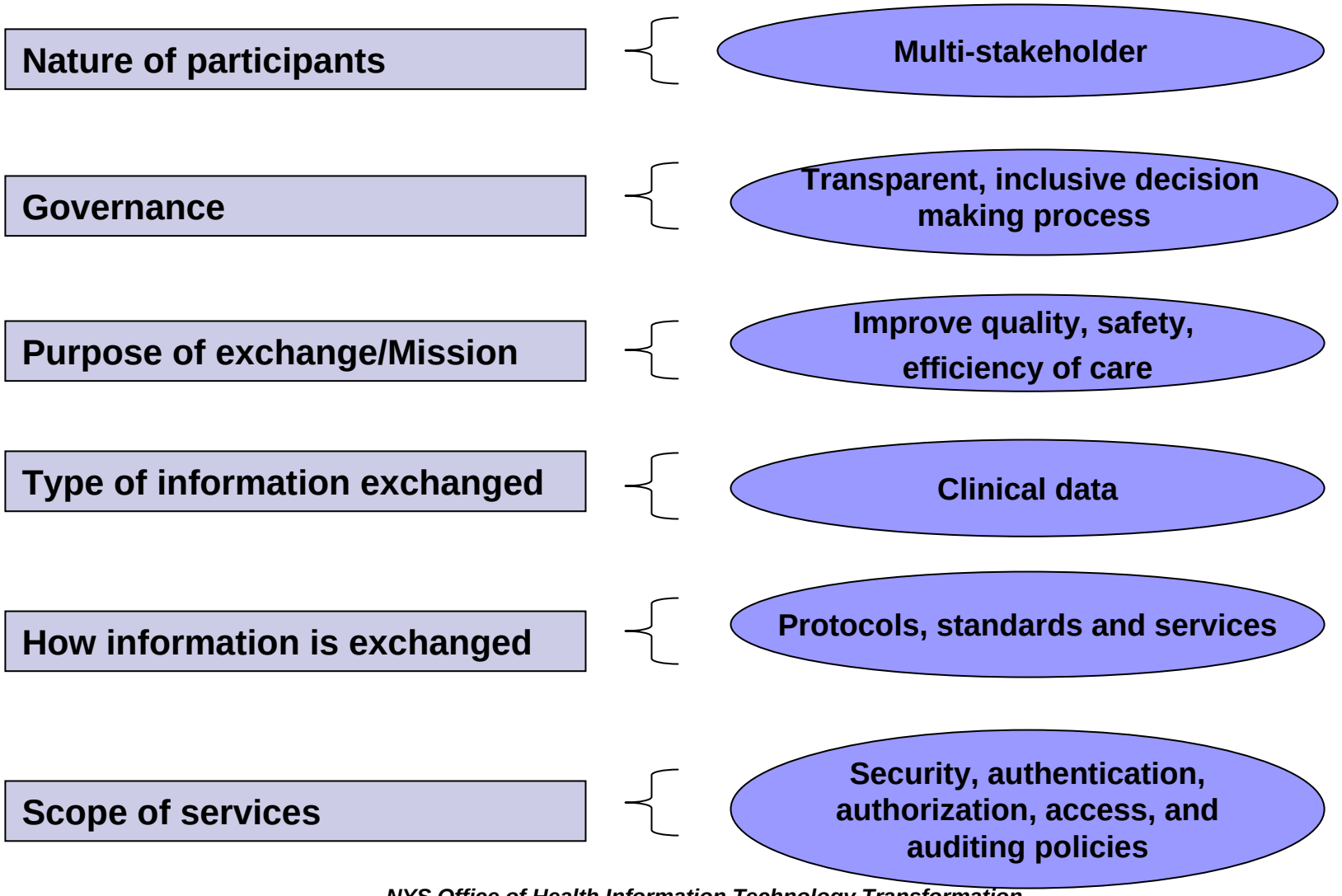
New Policy Framework for RHIO Consent Rules



Implementation of New Consent Law and Policies



Six Critical Components of the RHIO Definition



“Strawman”: Standardized Consent Policies for RHIOs

Key Principles of New Consent Policies and Procedures

Policies and procedures should:

- Facilitate consumer choice and address consumer concerns about privacy
- Promote exchange of information to improve the quality and efficiency of care
- Provide RHIOs with operational flexibility
- Be practical and “implementable” for RHIO participants
- Be simple and clear with a concrete rationale
- Be agnostic on technology model
- Serve as the minimum set of requirements. RHIOs may choose to exceed these policies and procedures.

Terms and Definitions

Term	Definition
Statewide collaboration process	A process involving multiple and diverse stakeholders in an open and transparent dialogue, sanctioned by the NYS Department of Health, that will inform the development of policies and procedures for RHIOs.
Consent policies and procedures	Standards and practices for RHIOs relating to consumer consent developed through the statewide collaboration process and approved by the State Department of Health.
Strawman	Mock recommendations proposed to facilitate discussion and drive consensus toward concrete policies and procedures for RHIOs.

Strawman: Defining a RHIO for the Purpose of Consent

Key Policy Questions for RHIO Consent Rules

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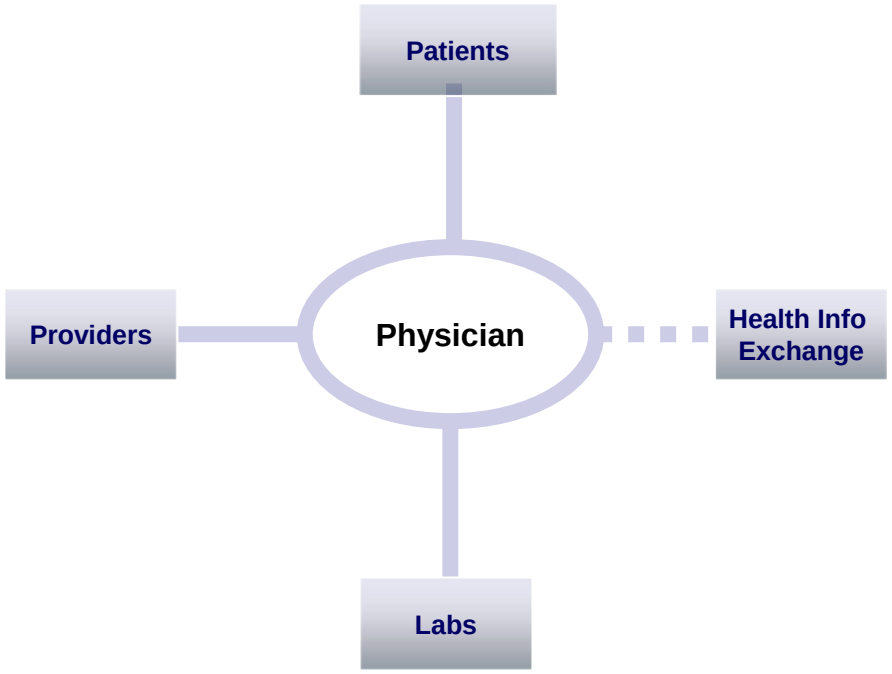
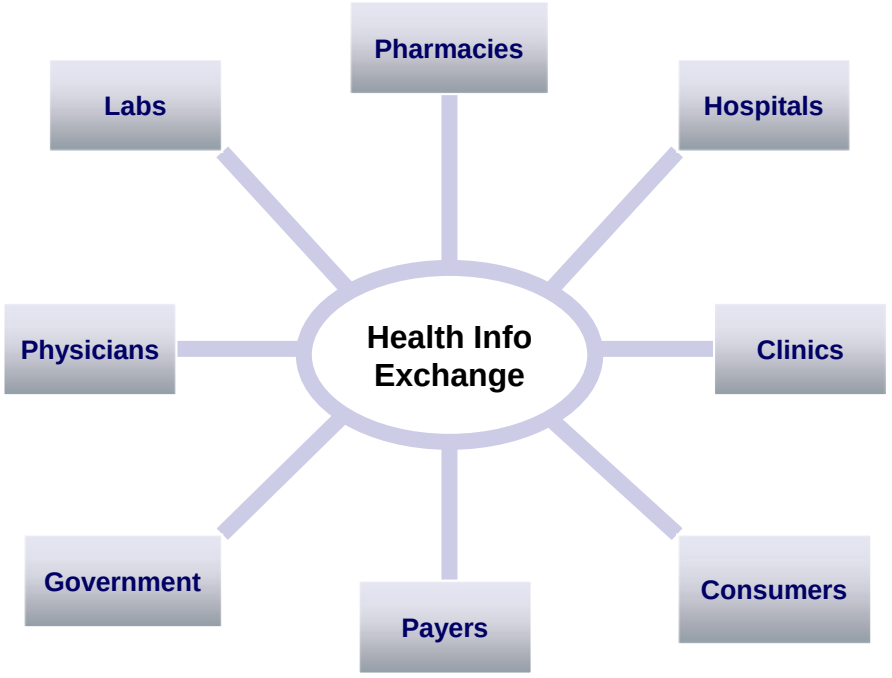
Health Information Exchange Options

Physician Centric Health Information Exchange ("One to One Exchange")



Community-wide Health Information Exchange (RHIO)



RHIO Definition: How Information is Exchanged

Definition of Issue

What are the criteria and who has the authority to ensure compliance with organizational and technical requirements related to consent?

What are the criteria to determine what exchanges fall outside the RHIO definition? E.g. One-to-one exchanges for hospital look up or results delivery

Considerations

- One-to-one exchanges generally are adequately governed by current law. Imposing new requirements could prove unnecessarily disruptive.
- It is not always clear what falls within a one-to-one exchange
- RHIOs facilitate data exchange between providers and others that do not necessarily relate to each other clinically in a direct way (e.g. no referral, test order, etc.)
- There is potential for confusion and inconsistency across RHIOs if different standards exist for different types of HIE within a RHIO
- New consent policies should promote continuity and create a migration path for projects engaged in one-to-one exchanges to become a RHIO and eventually link to a SHIN-NY
- To build trust, consumers should know that all RHIOs are adhering to “minimum privacy standards”
- NYS should inform and support work in progress on national standards on RHIO accreditation (e.g. CCHIT, AHIMA)

Strawman: Scope of HIE Activities Governed

Recommendation

- New consent policies apply only to RHIOs and their participants.
- RHIOs must adhere to minimum protocols, standards, and services, developed by a statewide collaboration process and approved by the State, which apply to the full scope of RHIO services, including consent policies.
- All information exchange taking place through a RHIO must comply with the RHIO protocols and standards related to consent.
- Minimum protocols, standards and services serve as the floor for RHIO policies and practices. RHIOs may choose to implement policies and practices that exceed the protocols, standards and services defined by the State.
- RHIOs must ensure the health information service providers with whom they contract and the participants of the RHIO comply with the minimum protocols, standards, and services of the new consent policies and procedures.

Strawman: How Information is Exchanged

Recommendation

- A Regional Health Information Organization (RHIO) is defined as a multi-stakeholder organization with a transparent, inclusive decision making process, whose mission is to improve quality, safety and efficiency of care through the exchange of clinical health information.
- Specific criteria and standards for defining a RHIO will be developed by a statewide collaboration process and approved by the SDOH relating to the following:
  - Nature of participants
  - Governance
  - Purpose of exchange/Mission
  - Type of information exchanged
  - How information is exchanged
  - Scope of services
- This definition recognizes that:
  - A RHIO's use cases and business model can vary due to the geographic breadth and its types of activities and may be determined by the market place in which it operates; and
  - Important health information exchange projects can exist outside of a RHIO context e.g. those which involve pushing information from one application to another where a user is currently operating under current law to do so. Such entities can continue to conduct these activities without RHIO designation, if they so choose.

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

Key Policy Questions for RHIO Consent Rules

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Obligations of Participation

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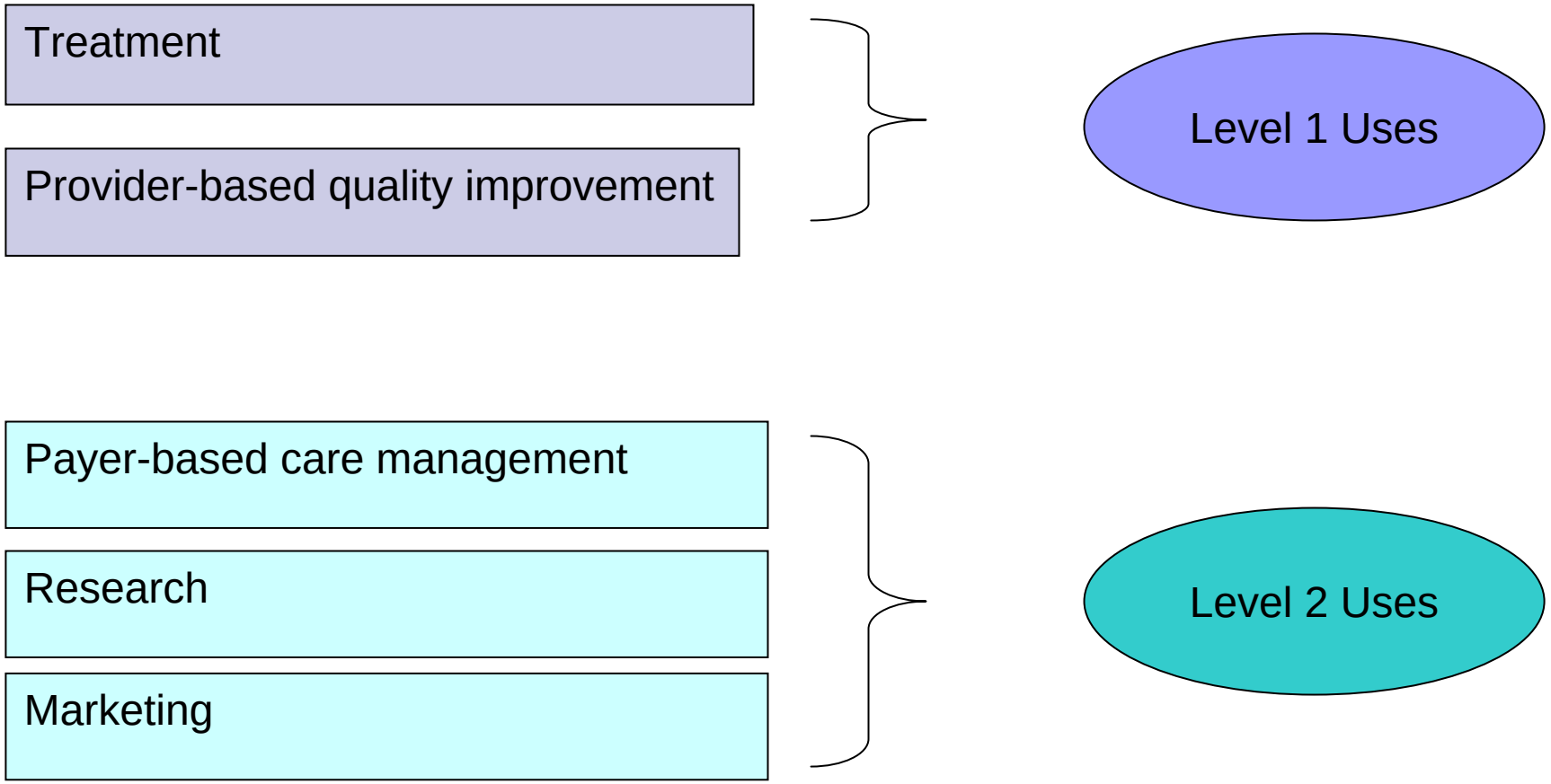
Identifiable Data

- New consent policies and procedures for RHIOs in New York State apply only to identifiable health information
- Consent policies and procedures for the use of de-identified data exchanged through a RHIO will be developed through the statewide collaboration process and approved by the State
  - According to HIPAA, “de-identified health information neither identifies nor provides a reasonable basis to identify an individual.”
- Use of information for public health reporting does not require consumer consent but may be integrated into consumer education efforts.

Core Issues Regarding Uses of Information (Identifiable Data)



Definition of Uses of Information – Level 1

Treatment

- The provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party. A third party is an entity with whom a health care provider has a contractual relationship related to the provision, coordination or management of health care and related services for a consumer. Under this contractual relationship, the health care provider must ensure that the contracted entity adheres to new consent policies and procedures;
- Consultation between health care providers regarding a patient; and
- The referral of a patient from one health care provider to another.

(Source: Modified from HIPAA)

Provider-based quality improvement

Activities by a provider and/or its contracted entities that include:

- Conducting quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, and case management and care coordination; and
- Disease management which can include a range of activities that involve the provider-controlled exchange of consumer health information with third parties with whom the provider has a contractual relationship related to the provision, coordination or management of health care and related services for a consumer.
- Third party entities may include health plans
- Such activities may be facilitated through the RHIO.

(Source: Modified from HIPAA)

Definition of Uses of Information – Level 2

Payer-based care management

Activities by a health plan that include:

- Conducting case management and care coordination; and
- Disease management which can include a range of activities through which the health plan has direct access to patient-identifiable clinical data without the provider serving as an intermediary.

(Source: Modified from HIPAA)

Research

- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

(Source: HIPAA)

Marketing

- Any communication about a product or service that encourages recipients to purchase or use the product or service.
- An arrangement whereby a RHIO participant and another entity discloses consumer health information, in exchange for direct or indirect remuneration, for the other entity to communicate about its own products or services encouraging the use or purchase of those products or services.

(Source: HIPAA)

Should the consent process vary according to use of information?

Definition of Issue

Should different uses of information require different standards of consent?

Considerations

- Consumers ultimately have the right to consent to any kind of use. Some uses of information are likely to be more acceptable and predictable to consumers than others (e.g. treatment, payment as they bring direct personal benefit).
- Other uses are less likely to be expected e.g. research and marketing and may not bring direct personal benefit.
- For unexpected uses, more intensive efforts are necessary to ensure the consumer understands that they are consenting for these uses of health information.
- Multiple standards of consent can build patient trust. However, multiple standards will be more burdensome to implement.
- Provider-based quality improvement is a Level 1 use and thus should be subject to Level 1 consent standards
- Payor access to additional clinical information may require a higher level of consent

Strawman: Uses of Information

Recommendations

- Consent policies will be determined by the use of the information. Uses of information will be defined as:
  - Level 1, which includes information exchange with providers for the purposes of treatment and provider-based quality improvement.
  - Level 2, which includes payer-based care management, research, marketing and other uses that are not Level 1 or prohibited.
- Definitions for uses described above will be developed through the statewide collaboration process and approved by the State.
- Consent requirements for Level 1 and Level 2 uses will differ, with a more streamlined process for Level 1 uses and higher restrictions for Level 2 uses.
- While RHIOs play an important role in facilitating public health reporting, consent is not required under current law. Consent rules for public health will not change under new consent policies and procedures.
- Certain uses of information exchanged by or received from RHIO participants will be prohibited. Prohibited uses include underwriting and other such uses as may be designated by the statewide collaboration process and approved by the State.

Obligations of Participation

- Obligations: What are the core obligations of a RHIO with respect to consumer consent policies?
  - Uses of information
  - Where and by whom consent is obtained
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  - Audit and transparency

Where and by whom should consent be obtained?

Definition of Issue

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

To what extent do consumers have the opportunity to decline participation of providers?

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

Should there be break the glass capacity? Should emergency room personnel be required to ask for consent if the patient is conscious?

Considerations

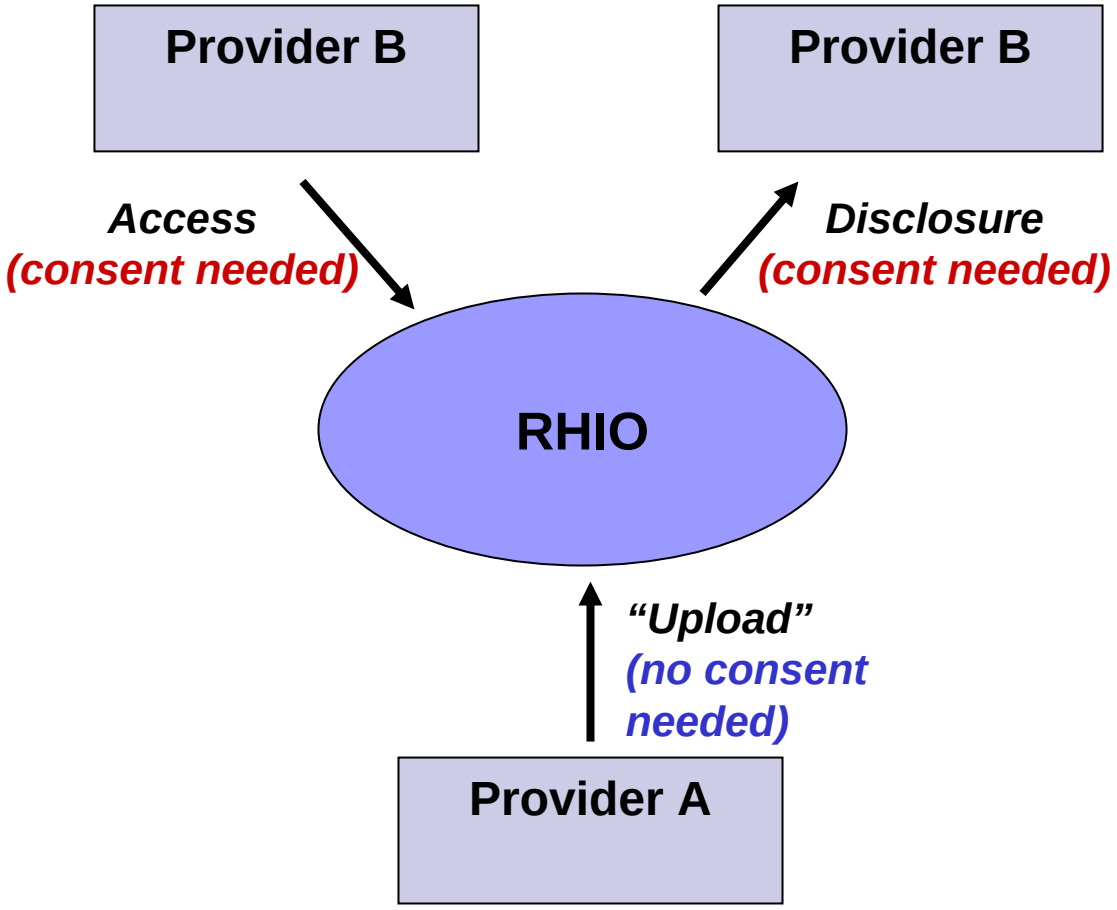
- Many options for obtaining consent include:
  - One-time consent per exchange (at RHIO level)
  - One-time consent with per-provider, per visit affirmation
  - Multiple consent obtained per provider
- Loading data into a technology platform is a business associate-type arrangement that is not generally considered a “disclosure” under current law if the provider holds the data and no other entities have access to it prior to consent.
- Need state guidance on what level of demographic data can be viewed prior to consent
- Will RHIOs be required to track patient refusals to grant consent?

Strawman: Where and By Whom Consent is Obtained

Recommendations

- RHIOs must obtain an affirmative consent from consumers prior to sharing their information among its members.
- In an emergency situation in which the consumer is unconscious or otherwise unable to give or withhold consent, and the treating clinician determines that data that may be held by the RHIO may be material to treatment, and the consumer has not previously withheld consent for the provider to access his/her data, the RHIO may allow the physician to access the consumer's data through “break the glass” capability. The physician must attest that all of these conditions apply, and the RHIO software must maintain a record of this access.
- Data may be uploaded to the RHIO prior to receipt of consent, in accordance with RHIO consent policies and procedures.
- Consent to exchange consumer data through the RHIO can be obtained at any location by any participating clinician or health care organization in the network or individual authorized by the RHIO.
- These rules apply equally for Level 1 and Level 2 uses.

Consent and Movement of Data



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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.

- 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 ability to restrict data by encounter
- Option 4: Consumer given a choice of not participating in exchange (all in or all out)

Considerations

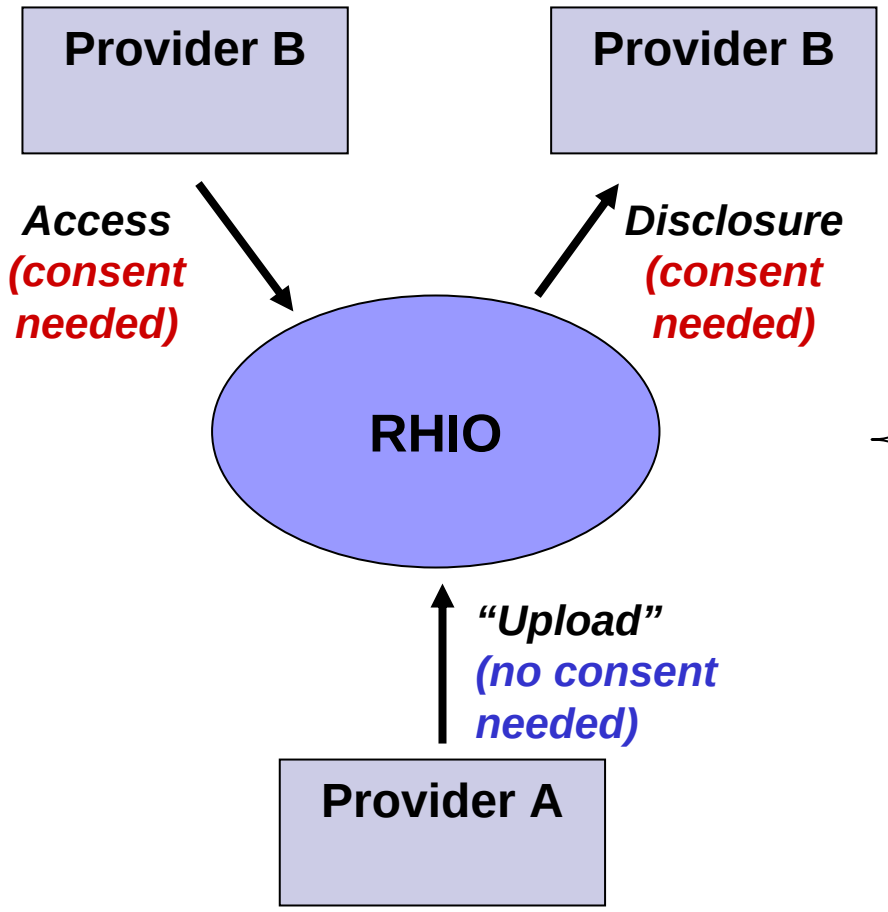
- Consumers may want to control access to sensitive information that may lead to discrimination
- Excluding sensitive health information can compromise quality of care and/or create financial and operational burdens for RHIO/provider
- Concerns exist about reliability and complexity of restricting information by discrete data elements.
- Stigma may be associated with option 4 for consumers who do not participate and with including a “flag” on medical record indicating sensitive information
- Under state law, special protections exist for certain types of information e.g. HIV, substance abuse, mental health
- RHIO participants are likely to change over time and consumers should be able to easily access a participant list.

Strawman: Provider Participation and Sensitive Information

Recommendations

- To ensure that consumers have knowledge of which participants are involved in the exchange through the RHIO, consumers must be given written notice that the participant is involved in the RHIO prior to the consumer's health information being exchanged by the participant. The notification is not necessary prior to data upload. Written notification may be incorporated into the affirmative consent.
- RHIOs must provide consumers with the ability to exclude selected providers from disclosing and accessing their health information through a RHIO. Such exclusions need not be at the individual clinician level, but may be done at an organizational level (e.g. medical practice, hospital).
- RHIOs and providers must make available, upon request, an updated list of RHIO members to the consumer. Standards for periodically updating RHIO membership will be determined through the statewide collaboration process.
- A single consent may be obtained to exchange all health information, including HIV, mental health and genetic information, which must specifically be referenced in the consent form.
- RHIOs and their participants may, but are not required to, offer consumers the ability to screen certain types of sensitive information from RHIO exchange.
- Consent to exchange information from designated substance abuse providers is subject to current Federal law. Through the statewide collaboration process, guidance on the exchange of substance abuse data will be developed.
- These rules apply equally for Level 1 or Level 2 uses

Consent and Movement of Data



- **No consent needed for upload of consumer health information**
- **Single affirmative consent can suffice for disclosure/access of consumer's health information**
- **Consumer must be notified of provider organization's participation before the provider organization may disclose/access the consumer's health information through RHIO**
- **Consumer must have ability to prevent disclosure/access of information by designated provider organizations**

Potential Operational Examples

ONE-TIME AFFIRMATIVE CONSENT

1. **Upload:** Information uploaded to RHIO without consent
2. **Consent:** RHIO obtains one-time, durable affirmative consent from consumer authorizing all current and future provider organizations in RHIO to disclose or access patient data through the RHIO.
3. **Notice of Provider Organization Participation:** Before a provider organization may disclose or access patient information through the RHIO, the patient must be notified that the provider organization is participating through, for example
   - Provider organization mailing notice to patients
   - Provider organization giving notice of participation at patient visit or
   - Consent form including list of participating provider organizations and updating patients regarding new participants.
4. **Provider Exclusion:** Consumer may contact RHIO or provider organization to exclude provider organization from disclosing and accessing consumer's health information through the RHIO.

MULTIPLE AFFIRMATIVE CONSENTS

1. **Upload:** Information uploaded to RHIO without consent
2. **Consent:** Each provider organization obtains durable, affirmative consent from consumer authorizing the provider organization to disclose and access patient data from all current and future provider organizations in RHIO
3. **Notice of Provider Organization Participation:** Consent serves as notice of provider organization's participation
4. **Provider Exclusion:** In cases where consumers do not consent, provider organizations are excluded from disclosing and accessing consumer's health information through the RHIO.

Obligations of Participation

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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 will improve consistency across RHIOs
- Standardized consent form provides consistency but reduces RHIO participant flexibility (may be too constraining)
- Listing participants is difficult due to regular changes in provider membership. An alternative is to include on consent form a link to web site that lists participants and is regularly updated
- Group should explore whether RHIO's eventual accreditation status and/or participation in SHIN-NY should be on form

Strawman: Standardized Consent Process

Recommendations

- A standardized consent form will be developed through the statewide collaboration process and approved by the State for use by RHIOs. For RHIOs that choose to develop their own form, the State will provide standard requirements and approve customized forms.
- The standardized consent form required for Level 1 uses must include:
  - A description of the intended uses;
  - The consumer's right to limit which participants have/provide access to information;
  - What information is being exchanged including specific reference to HIV, mental health and genetic information, if applicable;
  - The consumer's right to revoke consent; and
  - Information about who is participating in the exchange including through data sharing relationships with other RHIOs.
- Consent for Level 2 uses must include all of the above plus specific information about:
  - With whom information will be disclosed
  - For what purpose
  - Whether information is subject to re-disclosure
  - Whether the RHIO or its participants will benefit financially from exchange of the data
  - The date of expiration of the consent.

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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.
- Minors who turn 18 may decide not to include their information in the community-wide exchange.
- Time-limited consent for Level 1 can be confusing and burdensome for providers.

Strawman: Durability and Revocability

Recommendations

- Consent for Level 1 uses are not time-limited but can be revoked at any time and at any location (at location of participating clinician or health care organization serving the consumer in the network).
- Consent for Level 2 uses must be time-limited for a period of no greater than one year.
- When a minor participating in the RHIO turns 18, consent to participate in the RHIO must be obtained. (Additional guidance relating to consent for exchange of consumer health information on minors will be developed through the statewide collaboration process and approved by the State.)
- Consumers must be notified in writing of the right to revoke consent to participate in the RHIO and/or to exclude a provider's participation upon the following events:
  - After a positive HIV/AIDS diagnosis
  - When health care proxy assumes decision-making
  - When use of information changes
- Revocation of consent prevents future data from entering the exchange and makes previously-uploaded data inaccessible through the RHIO. However, any provider who has already accessed and imported the consumer's health information into their medical record can continue to use it as part of their medical record.

Obligations of Participation

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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

- Integral to education effort is determining how much information will be shared with patient (e.g. uses, right to revoke, etc.)
- Need to determine education process for special populations e.g. deaf, blind and hard of hearing population, immigrants
- 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

Strawman: Consumer Engagement and Informed Consent

Recommendations

- RHIOs must conform to consumer education program standards developed by a statewide collaboration process and approved by the State Department of Health.
- RHIOs must appoint at least one consumer representative to its Board. A consumer representative is defined as a person whose interest in the RHIO is as a patient or representative of patients and who does not otherwise participate in or have a financial interest in the operation of a RHIO.

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

- A viable and transparent audit process will ensure patient trust
- Disclosure of breach may raise issues of liability
- Discipline options after breach could include:
  - Expel participant from RHIO
  - Loss of provider license
  - Financial penalties
- While robust penalties provide a deterrent to deliberate breach, fear among providers of inadvertent breach could deter participation
- Remedy options after breach
  - Remuneration for emotional and physical harm caused by wrongful disclosure

Strawman: Audit and Transparency

Recommendations

- RHIOs (or third party designated by RHIO) must conduct periodic audits no less than annually.
- Audit reports, including identification of breaches, must be submitted regularly to the Board, no less than annually.
- RHIO participants are required to inform the consumer of breach of disclosure of the consumer's health information immediately upon detection.
- RHIOs and providers must make available to the consumer upon request an audit trail of the consumer's health information accessed through the RHIO.

Strawman: RHIO-to-RHIO Transfers

Recommendations

- Before RHIOs may exchange information with another RHIO(s), they must enter into a contractual agreement with the other RHIO(s) requiring compliance with consent policies and procedures.

Facilitated Discussion: Principles of New Policy Framework for Consumer Consent

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?
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- 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?

What are the consequences, including benefits and penalties, of meeting previously-defined obligations?

Definition of Issue

Meeting obligations defined by the State are aligned with benefits and penalties.

- Compliance with obligations should bring meaningful benefits.
- Non-compliance with obligations can result in penalties for RHIOs.

Considerations

- Benefits of complying with consent policies?
  - Access to HEAL and other funding
  - Access to Medicaid data
  - Accreditation
  - Protection from liability
- Penalties of not complying with consent policies?
  - Loss of benefits described above
  - Financial penalties
- Should new penalties be created for participants who use consumer health information to discriminate against the consumer?

Recommendations

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?
  - 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?

How and by whom will adoption/compliance be enforced?

Definition of Issue

To ensure that RHIOs are able to access benefits and are subject to penalties for not adhering to obligations, an entity must be designated as an enforcement body.

Should there be additional laws e.g. private laws of action?

Do we need further law beyond current legal requirements and participant agreements?

Considerations

- Should the benefits be limited only to RHIOs who comply with obligations or are other exchanges eligible?
- Should the penalties be limited only to RHIOs who do not comply with obligations or are other exchanges eligible?
- Additional state law may be burdensome
- Ensure that violations for disclosure breach are similar re: paper-based and electronic exchange
- Compliance should be enforced by independent entity

Recommendations

- Planning efforts are underway to develop an accreditation process and framework for RHIOs
- In the immediate term, RHIO compliance with obligations can be ensured through:
  - Contractual relationships between the State and RHIOs e.g. HEAL and other funding
  - Data sharing agreements with the State e.g. Medicaid data

Next Steps

Next Steps

- DOH will post on its web site a white paper for public comment
- White paper will summarize findings from meetings and make policy recommendations