Agenda

- Welcome and Introductions
- Meeting Purpose and Goals
- Review of Process to date
- Facilitated Discussion
- Next Steps
NY HISPC Part 2: Project Focus

- RHIOs have responsibility for ensuring privacy and security of information collected and exchanged
  - Access and use policies
  - Authentication of identity
  - Authorization for access
  - Consumer and provider identification
  - Transmission security
  - Data integrity
  - Audit trails for clinicians and consumers
  - Administrative and physical security
  - Enforcement and Protections
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
Review of Process
NY HISPC Part 2
Project Timeline and Process Steps: July 2007-Dec 2008

- **July:**
  - Project Kickoff and Planning

- **August-September:**
  - Facilitate Stakeholder Meetings

- **October:**
  - Propose Strawman Recommendations
  - Post White Paper and Solicit Public Comments

- **November-January:**
  - Facilitate Stakeholder Meetings

- **February:**
  - Categorization and Analysis of Comments

- **March:**
  - Facilitate Stakeholder Meeting

- **April:**
  - Final Policy Guidance and Adoption regarding HEAL 5 awards

- **May-December:**
  - Ongoing HISPC Effort and Statewide Collaboration Process

*NYS Office of Health Information Technology Transformation*
## Terms and Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statewide collaboration process</td>
<td>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.</td>
</tr>
<tr>
<td>Consent policies and procedures</td>
<td>Standards and practices for RHIOs relating to consumer consent developed through the statewide collaboration process and approved by the State Department of Health.</td>
</tr>
</tbody>
</table>

Department Of Health

New York eHealth Collaborative Board

Governance

- Education & Communication Committee
- Policy & Operations Council (RHIOs, HSPs, CHITAs)

Strategic Partner Initiatives
- Financial Sustainability & Incentives
- HITEC – Evaluation
- Consumer Advocacy Coalition

Collaborative Work Groups
- Clinical Priorities
  - Quality Reporting
  - Public Health
  - Medicaid
  - Connecting NYs and Clinicians
- Protocols & Services
- Privacy & Security
- EHR Collaborative

Implementation

Policies & Standards

Feedback

Projects
- HEAL Teams
- NHIN Team
- CDC Team

NYS Office of Health Information Technology Transformation
New Policy Framework for RHIO Privacy & Consent Rules

Mechanism for New Policy Framework

- Legislation
- Regulation
- Contracts
- Accreditation

Obligations
Adhere to standardized privacy & 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
Implementation of New Consent Law and Policies

Laws

Policies

RHIO

Participation Agreement

Participant

Participant

RHIO

Participation Agreement

Participant

Participant

RHIO

Participation Agreement

Participant

Participant

NYS Office of Health Information Technology Transformation
<table>
<thead>
<tr>
<th>Nature of participants</th>
<th>Multi-stakeholder &amp; All Consumers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Governance</td>
<td>Transparent policy framework, inclusive decision making process</td>
</tr>
<tr>
<td>Purpose of exchange/Mission</td>
<td>Improve quality, safety, efficiency of care</td>
</tr>
<tr>
<td>Type of information exchanged</td>
<td>Clinical data</td>
</tr>
<tr>
<td>How information is exchanged</td>
<td>Protocols, standards and services via SHIN-NY</td>
</tr>
<tr>
<td>Scope of services</td>
<td>Security, authentication, authorization, access, and auditing policies</td>
</tr>
<tr>
<td>Consumer Access</td>
<td>Provisions for ensuring consumer access to and control of data</td>
</tr>
</tbody>
</table>
Key Principles of New Consent Policies and Procedures

Policies and procedures should:

- Promote patient-centered care by facilitating consumer choice and addressing consumer concerns about privacy
- Promote exchange of comprehensive information ensuring clinical effectiveness to improve the quality and efficiency of care
- Minimize burdens on healthcare providers
- Be practical and “implementable” for RHIO participants providing operational flexibility
- Be simple and clear with a concrete rationale
- Foster innovation while ensuring public trust
- Be neutral on technology model
Affirmative and Informed Consent Recommendations

- Any New Yorker has the right to not participate in interoperable HIE enabled by the RHIO
- If a patient grants consent to participate, they have a right to prohibit provider organizations of their choice to access their PHI
- The patient consent permits provider organization access to PHI for treatment, quality improvement and disease management
- The patient consent permits health plans, employers and other third parties access to PHI for quality improvement and disease management
- Provider organization can then access all PHI, including sensitive information from all providers participating in interoperable HIE
- Patient is informed about all participating providers in the RHIO and how updates to the participant list can be obtained
- Patient gives consent at the provider organization level and allows access to patient’s PHI by all authorized individuals in the organization to the extent needed
- Uses are limited to treatment, quality improvement and disease management
Operational Considerations

- Provider level services
- RHIO level services
- Health plan services
- Physician and consumer audits
Health Information Exchange Options

Physician Centric Health Information Exchange
(“One to One Exchange”)

Interoperable Health Information Exchange
(RHIO as governance entity)

Physicians

Labs

Government

Consumers

Payers

Clinics

Hospitals

Pharmacies

RHIO:
Governance
HIE:
SHIN-NY

Physician

Health Info Exchange

Providers

Patients
Level 1 and Level 2
Uses of Information

Level 1 Uses
- Treatment
- Quality Improvement & Disease Management

Level 2 Uses
- Research
- Marketing
The Process Going Forward

- Analysis of public comments facilitated through NYeC to address definitions, clarifications and other concerns related to white paper:
  - Research, quality and marketing
  - Provider and consumer views on the implementation of the consent process
  - Payer/plan uses and roles
  - Sensitive health information and sensitive population needs
  - Enforcement and protections
  - Outstanding issues
  - Glossary and definitions
- Public forum on March 10 will provide opportunity to discuss key issues provided during the public comment period
- NYeC Board reviews and makes recommendations
- Final policy document and standardized consent form developed and issued by NYSDOH
- HEAL 5 contracts will include language on consent policy implementation
- Accreditation project exploring regulatory framework regarding other key privacy policies that need to be coupled with consent policy
- Ongoing participation in HISPC process throughout 2008
Research
## Research

### Definition of Issue

1. As currently drafted, White Paper requires Level 2 Consent for all research. Level 2 consent, which requires more specific information than Level 1, may unnecessarily restrict research performed by and for RHIOs.

2. There is uncertainty as to which IRB may review research involving data in the RHIO.

3. Level 2 Consent for research should not conflict with current legal requirements.

### Considerations

1. RHIOs need to perform research evaluations in order to assess effectiveness in collaboration with HITEC. IRBs assess whether proposed research studies present risks to patients and whether consent from patients is required. Some RHIO research will qualify for IRB waivers of consent and of HIPAA Authorization. For such IRB-waived research, further consent is not legally necessary.

2. There are a variety of IRBs that might appropriately grant approval for research involving data in a RHIO, including a provider’s own IRB, the DOH IRB, a university’s IRB and national IRBs.

3. IRBs impose various requirements on researchers, including the contents of consent forms to be used, if any.
Recommendations

1. Research evaluations involving RHIOs should be consistent with current IRB and HIPAA law and not impose additional restrictions.

2. For example, RHIOs should be able to engage in and facilitate research in these circumstances:
   
   a. If research receives IRB waiver of consent and HIPAA authorization, exempt such research from any further consent requirements (i.e. neither Level 1 nor Level 2 consent applies to IRB-waived research).
   
   b. RHIOs and RHIO participants are entitled to use any IRB to review and approve of research involving data in the RHIO.
   
   c. For research where IRB requires informed consent and HIPAA authorization, there needs to be consistency between requirements in the White Paper and requirements by the IRB.
   
   d. This does not apply to de-identified data.
Provider and Consumer Views on Implementing the Consent Process
# Operationalizing Consent & Revocation

## Definition of Issue

1. Under affirmative consent for a provider organization to access a patient’s data, what alternative approaches to implementing consent would comply with the intent of the HISPC white paper?

## Considerations

Comments suggested the following approaches to implementing affirmative consent and revocation.

1. Allow patients to review a list of all provider organizations in a RHIO (rather than signing separate consents for each provider organization) and check either those:
   - a. s/he wants to grant consent for, or
   - b. s/he wants to deny consent for

2. Allow patients to access the same list on-line and grant consent electronically rather than in paper form.

3. Allow patients to review a list of all providers having their consent and revoke consent for specific provider organizations with one transaction, whether in paper form or on-line.

4. Allow RHIOs to administer the consent and revocation process on behalf of provider organizations.
Operationalizing Consent & Revocation

Recommendations

1. Allow a RHIO to manage an affirmative and informed patient consent and revocation process on a provider organization’s behalf.

2. If a RHIO can implement an affirmative and informed consent process on a provider organization’s behalf as described in previous slide, these should be accepted as equivalent to the consent process recommended in the HISPC white paper.

3. The consent is only for the provider organizations listed on the form at the time the patient gives consent. As more provider organizations join the RHIO, the patient will need to grant or withhold consent for them subsequently.
## Clarifications

<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Once a provider organization has received a patient’s consent to access his/her data, it should be able to access that data from all provider organizations and RHIOs as long as the patient has a way to find out which ones it participates with.</td>
<td>1. This is the principle proposed in the HISPC white paper. The patient must receive a list of provider organizations whose data is accessible through the RHIO at the time s/he gives consent, and subsequent updates must be posted to the RHIO’s website or otherwise made available to the patient.</td>
</tr>
<tr>
<td>2. Clarify one-to-one or ‘push’ transactions that are not subject to the proposed consent policy.</td>
<td>2. One-to-one transactions are those where data from one provider are pushed or made available to another without the second provider having access to other data in the RHIO.</td>
</tr>
</tbody>
</table>
### Clarifications

<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Clarify ‘break the glass’ provisions.</td>
<td>3. The principle is that if a patient is unconscious or otherwise unable to grant or withhold consent, and the physician finds that accessing the patient’s information is important for clinical care, and the physician certifies in the RHIO software to both these points, and the patient has not previously withheld consent from that provider organization, then the RHIO will disclose the data to the physician and will log this access as ‘break-the-glass.’</td>
</tr>
<tr>
<td>Definition of Issue</td>
<td>Clarification</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>4. Do privacy and consent policies differ between RHIOs that are owners of the patient data as opposed to those who are custodians of patient data that is owned by the provider organizations?</td>
<td>4. The privacy consent requirements are the same for owner and custodian RHIOs. However, a RHIO that owns patient information must also comply with requirements of HIPAA as a covered entity. Under the custodial model, RHIOs are business associates of provider organizations and it is the provider organizations that must comply with HIPAA.</td>
</tr>
</tbody>
</table>
Clarifications

Recommendation

1. Amend the proposed HISPC white paper to reflect these clarifications.
### Complications for Hospitals & Medical Centers

<table>
<thead>
<tr>
<th>Definition of Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Comments addressed the burden and complications experienced by many provider organizations that are implementing consent policies by modifying their ADT systems to record consent, modifying their registration workflows, and adding steps to the registration process to determine the state of a patient’s consent.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. It is acknowledged that implementing the affirmative consent process will result in complications and changes in workflow, but that these changes will achieve the principles of interoperable HIE consent outlined in the HISPC white paper.</td>
</tr>
</tbody>
</table>
Complications for Hospitals & Medical Centers

Recommendation

1. Affirm that provider organizations and RHIOs are free to choose their own operational methods for managing affirmative and informed consent processes.

2. Begin developing requirements and standards for SHIN-NY consent services through the statewide collaboration process to interconnect to provider-level consent systems.
## Physician / Clinician Issues

### Definition of Issue
1. Unclear to the patient whether the practice office is considered part of the “provider organization” and therefore included in the patient’s consent.

### Clarification
1. Proposed response: encourage provider organizations to make clear in the interoperable HIE policies they give to patients, which practice offices and other sites are included in the provider organization.
Physician / Clinician Issues

**Recommendation**

1. Amend the proposed HISPC white paper to reflect these clarifications.
**Physician / Clinician Issues**

**Definition of Issue**
1. Time consuming and difficult workflow issues for providers regarding determining if patients have already given consent to someone else in the same organization may decrease provider use of the system.

**Considerations**
1. A specific physician in a practice office that is included in a larger provider organization that has already gotten consent by a different provider, may decide that the effort to check whether the patient has previously made a consent decision, and to obtain the patient’s decision now if he/she has not already done so, is simply too great for the practice staff to take on. In that case, the physician may still inquire into the HIE software for the patient’s data, but unless another registration point has already recorded the patient’s consent, the physician will not be able to access any data.

2. If the process is too difficult, clinicians are likely to resort to alternative methods of data access such as through remote access to individual hospital and other systems and/or fax.
Physician / Clinician Issues

<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Time consuming and difficult workflow issues for providers regarding determining if patients have already given consent to someone else in the same organization may decrease provider use of the system. (CONTINUED)</td>
<td>3. To reduce that frustration, some comments suggest that the RHIO or provider organization should be allowed to come up with their own methods to identify patients who have given consent such as giving the patient a sticker to affix to his/her insurance card, to indicate that he/she has given consent – if the patient doesn’t have the sticker, the physician won’t try to access the patient’s data through the RHIO.</td>
</tr>
</tbody>
</table>
Physician / Clinician Issues

**Recommendations**

1. Recommend that each RHIO be able to choose whether consent should be obtained by the RHIO on behalf of the provider organization or at the individual organizations (some RHIOs may choose to allow some organizations to do their own consent and others to be done by the RHIO).

2. Allow provider organization listings to also give the patient the opportunity to check a box allowing all providers to access their records (while at the same time including a complete list of who the providers are currently and a statement that this would not allow access by any future new organizations).

3. Acknowledge the logistical difficulty and affirm that a practice can decide not to collect consents, but in that case the physician will not be able to access patient data unless someone else (such as the RHIO) has already collected consent for their provider organization.
## Recommendations

4. Allow the RHIO to request, obtain and record the patient’s affirmative and informed consent to access his/her PHI on independent practices behalf, rather than requiring each practice to obtain this consent on its own.

5. Allow provider consent to cover multiple practice settings and allow the consent to follow both the patient and clinician at different practice sites. In this case, the RHIO will list all of the practices participating in the RHIO, and will give the patient the option to
   a. explicitly grant consent to all of these practices, or
   b. select specific practices to whom to explicitly grant consent, without granting consent to the others, or
   c. select specific practices from which to explicitly withhold consent, while explicitly granting consent to all the other practices.

6. Recommend that the patient’s initial consent not extend beyond the practices listed by the RHIO at the time of the initial consent. If the RHIO adds more practices/provider organizations into HIE in the future, the RHIO will need to make those additions known in a publicly-accessible notice, such as on the RHIO’s website. At that time, the RHIO may also highlight to the patient any new practices that have provided treatment to the patient, and ask the patient to grant consent to some or all of these new practices, by signing an amendment.
Physician / Clinician Issues

<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Access of information by providers outside of situations where patient written consent is obtainable</td>
<td>In the current care model:</td>
</tr>
<tr>
<td>1. Physician practice in call groups that often extend beyond their own organization. How can covering physicians access patient records while on call?</td>
<td></td>
</tr>
<tr>
<td>2. Physicians refer patients to specialists who often need to access the patients health data prior to the patient being seen by the specialist where in person consent could be obtained. It is important to access this information prior to the patient visit in order to expedite further testing etc that may be indicated. How can the specialist have permission to access patient information prior to the patient visit?</td>
<td></td>
</tr>
</tbody>
</table>
Physician / Clinician Issues

**Definition of Issue**

1. Access of information by providers outside of situations where patient written consent is obtainable (CONTINUED)

**Considerations**

3. Cross-covering physicians should be allowed to access patient records for patients of physicians they are covering as long as a patient consent has previously been obtained by the primary physician.

4. Referral physicians should be allowed to access patient records for patients referred to them by another physician as long as the patient has agreed to the referral to that physician organization. (This would also cover information such as lab reports that are “cc’d” to referral physicians)

5. When the patient is later seen at the referral physician organization a consent should be obtained before further access of medical information occurs.
Physician/Clinician Issues

Recommendation
1. The policy should reflect the above considerations.
## Transitional Suggestions

<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Determine an effective date for provider and RHIO adherence to the final HISPC consent policy.</td>
<td>1. Comments ranged from blocking all interoperable HIE until the state finalizes a consent policy and publishes consent forms, to allowing an 18 month transition period for compliance, to allowing RHIO experimentation with different approaches to consent before a policy is adopted.</td>
</tr>
<tr>
<td>2. Specify the content and timing for the release of the state’s standard consent form.</td>
<td>2. Comments included having the benefits of HIE included in the consent form and having the state publish the main policy points for consent by April 1 to allow providers and RHIOs under HEAL 1 to develop consent forms pending the state’s release of standard forms.</td>
</tr>
</tbody>
</table>
Transitional Suggestions

**Definition of Issue**

3. Develop a standard, statewide consumer HIE education program that emphasizes the benefits of HIE and provides standard information to prepare patients to grant or withhold consent when requested by a provider organization.

4. Allow provider organizations to combine HIPAA disclosure and HISPC consent into one form.

**Considerations**

3. A NYeC subcommittee has been formed to address how best to approach HIE communication and education statewide.

4. HIPPA and HISPC are inherently different processes. Under HIPPA, a patient only acknowledges a provider’s privacy practices whereas under HISPC, a patient affirmatively grants or withholds consent for access to his/her HIE data.
Transitional Suggestions

Recommendations

1. **Content and timing of release of consent forms:** The state should publish the main points in its final consent policy as soon as it is feasible to do so (such as April 15 or May 1). Consent forms should include information on the benefits of HIE to patients.

2. **Develop standard statewide education program.** Refer all comments to the NYeC communication and education subcommittee for consideration.

3. **Allow providers to combine HIPAA and HISPC forms.** These forms should *not* be combined given the inherent differences in these processes and that patients could acknowledge a provider organization’s HIPAA privacy practice but withhold consent for HIE.

4. **Continue HISPC process to further examine regulatory framework for patient consent and other privacy policies.**
Defining and Clarifying Third Party Level 1 Uses and Roles
# Defining and Clarifying Third Party Level 1 Uses and Roles

<table>
<thead>
<tr>
<th><strong>Definition of Issue</strong></th>
<th><strong>Considerations</strong></th>
</tr>
</thead>
</table>
| 1. How can consumer consent for health plans and others who perform quality improvement and care management activities to access PHI best be enabled? | 1. There are many entities, such as health plans and QIOs, i.e. IPRO, who can enhance the HIE value proposition by performing the Level 1 Use activities of quality improvement and care management. For purposes of this discussion, the term ‘health plan’ includes insurers, employers and other entities that pay for or provide health benefit plans to consumers.  
2. Any third party entity (collectively QI/CM entities) that performs quality improvement and care management activities should be able to follow the streamlined consent process for Level 1 Uses. |
<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How can consumer consent for health plans and others who perform quality improvement and care management activities to access PHI best be enabled? (CONTINUED)</td>
<td>3. Health plans support the affirmative and informed consent process outlined in the White Paper in order to provide transparency and consumer choice regarding the Level 1 Uses of medical information also described in the White Paper: Treatment and Quality Improvement and Care Management.</td>
</tr>
<tr>
<td></td>
<td>4. Various state and federal laws and regulations govern and permit the exchange of medical information among participants in the health care industry. This exchange takes place today using a range of modalities, from paper to electronic, to accomplish a range of purposes, from treatment to supporting health plan functions.</td>
</tr>
<tr>
<td></td>
<td>5. Different RHIOs are enabling different technological and administrative capabilities, as well as differing community standards, which will impact how third party access to a RHIO can be enabled.</td>
</tr>
</tbody>
</table>
Recommendations

1. RHIOs shall be permitted, not required, to contract with health plans and other third parties who perform quality improvement and care management activities, as those terms are defined in the White Paper, on terms mutually agreed to by the parties, subject to the following requirements:
   a. Affirmative and informed patient consent shall be obtained by the RHIO or other designated entity on terms consistent with the Level 1 Use consent requirements:
      1. A description of the intended uses;
      2. What information is being exchanged including specific reference to HIV, mental health and genetic information;
      3. The consumer’s right to revoke consent; and
      4. Information about who is participating in the HIE including through data sharing relationships with other RHIOs and how to stay informed about participants in real time.
### Recommendations

b. Uses of information by health plans and other third parties for quality improvement and care management activities shall be subject to consumer protection requirements, including a ban on the use of date for any reason other than Level 1 Uses. (For example, a ban on the sale of data for commercial purposes, a ban on the use of data for medical underwriting.)

c. The health plan or other third party must be specifically identified on the consent form; and the patient shall be given the option to grant or withhold consent to the specific plan or other third party.

d. Compliance with policies and procedures developed for RHIOs through the statewide collaboration process.

2. Based on the comments that we have received thus far, we are not recommending expanding the Level 1 Uses to include payment at this time.

3. Access to a RHIO by an entity that provides a PHR to consumers is outside the scope of this topic and will be addressed through the statewide collaboration process.
Addressing Sensitive Information and Sensitive Population Needs
Filtering

Definition of Issue
1. May a provider organization or a RHIO accommodate a patient’s request to prevent a specific bit of data, or data from a specific encounter, from being accessible through the RHIO?

Considerations
1. A patient who has given consent for provider organizations to access his/her data in the RHIO may want to exclude specific data from that access.
   a. This data is in the EMR of the provider organization and would otherwise be accessible through the RHIO, such as diagnoses, lab results, medications, etc.
   b. This may be sensitive data.
   c. It may be historic data that is not relevant currently, or it may be current data.
Filtering

**Definition of Issue**

1. May a provider organization or a RHIO accommodate a patient’s request to prevent a specific bit of data, or data from a specific encounter, from being accessible through the RHIO? (CONTINUED)

**Considerations**

2. Although the patient has given consent for access to his/her data by provider organizations, he/she may want to prevent access to this particular data either by all provider organizations, or only by specific provider organizations.

3. Providers have expressed a concern that the inability to view certain data may impede effective diagnosis and treatment.
   
   a. EG: the patient may want to prevent access to the fact that he has a prescription for Viagra, but if the doctor knew this it would change how he/she treats the patient for a cardiac event in the ED.

4. If the physician knows that the patient has withheld access to certain data, he/she can initiate a conversation with the patient to determine whether it is relevant to the current treatment, while still respecting the patient’s preference not to reveal data that is not relevant.
Filtering - Recommendation

**Recommendation**

1. RHIOs and their participating provider organizations shall be permitted, but not required, to allow a patient to prevent access to specific data while allowing access to other data; but if the patient has exercised that option, the record should carry an alert such as “At the request of the patient certain data has been withheld from this record.”
Minors

Definition of Issue
1. May a parent provide consent on behalf of his/her child for a provider to access health information about the child even when some information about the child may exist as a result of services for which the minor consented him/herself and without the parent’s knowledge?

Considerations
1. Minors have clear authority under NYS law to consent to treatment for various sensitive conditions (e.g. mental health, STDs, family planning, abortion, HIV testing, alcohol/drug treatment). Many of these laws contain provisions limiting and/or preventing the treating provider from disclosing information about such minor-consented services to the parent without the minor’s consent to such disclosure. However, virtually no electronic indicators are known to track the circumstances under which minors consent to services. Where the law allows minors to consent to treatment without parental permission or knowledge, the law would typically be interpreted to give the minor control over disclosure of the health information to third parties. At least one law (Article 27-F) appears to give the minor the sole right to release HIV-related information.
Minors

**Definition of Issue**

2. When a parent consents to RHIO access on behalf of his/her minor child, are there any further requirements with respect to consent when the child becomes emancipated? When child reaches age of majority?

**Considerations**

2. It is not realistic to assume that a provider and/or RHIO will be made aware of whether/when a child becomes emancipated.
Minors - Recommendations

Recommendations

1. When a minor consents to treatment without parental permission or knowledge, the minor’s consent is required to disclose information to third parties to the same extent that an adult’s consent would be required. In other words, the adult cannot consent on behalf of the minor in these circumstances. If a RHIO is going to provide access to health information of minors, it must ensure that a minor has provided consent to access to sensitive information as stated under considerations section (previous slide). If a RHIO is not able to accomplish this, the RHIO must not allow access to that minor’s information. RHIOS and providers using their professional judgment can decide to not to disclose specific information (data filtering).

2. RHIOs may accept consent from emancipated minors to the extent such emancipated status is known. However, it is also acceptable to rely on a consent previously granted by the parent of a (now) emancipated minor.
Incapacitated Adults

<table>
<thead>
<tr>
<th>Definition of Issue</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When a legally authorized representative provides consent on behalf of another person, is there any further requirement on behalf of provider/RHIO with respect to consent of the subject (i.e. if he/she regains capacity)?</td>
<td></td>
</tr>
<tr>
<td>2. New York State does not have a surrogate decision-making law and so relatively few incapacitated adults have legally authorized representatives.</td>
<td>1. There are no mechanisms currently in place that would reliably make a provider and/or RHIO aware that a patient has regained capacity. Moreover, the capacity status of certain patients may change back and forth within a short period of time.</td>
</tr>
<tr>
<td></td>
<td>2. Consent for admission to hospitals and skilled nursing facilities, and consent for treatment, is often granted on behalf of an individual by a person without legal authority. Spouses are not legally authorized to give consent on behalf of their spouse unless they have been appointed a health care agent (or have been appointed a guardian/conservator). Relatively few New Yorkers have appointed health care agents.</td>
</tr>
</tbody>
</table>
**Incapacitated Adults - Recommendations**

1. Legally authorized representative’s consent should be durable. However, statewide education should emphasize durable nature of legally authorized representative’s consent for RHIO participation so that individuals who regain capacity may know to follow up, if desired.

2. A renewed effort to enacting legislation would alleviate confusion and concern about getting the appropriately authorized legal representative to provide RHIO consent (and, for that matter, other NY consents for treatment and health care services).
Enforcement and Protections
## Standards

### Definition of Issue

1. How is breach defined in current law?

2. What current laws protect the confidentiality of health information, and when and how do those laws apply to health information maintained in RHIOs?

3. What are the requirements for security, auditing, authorization, authentication, differentiating emergency access?

### Considerations

1. Current law addresses confidentiality of health information including protections from disclosure and use in manner not authorized by law.

2. There is a need for clear understanding of all applicable confidentiality laws (federal and NYS) that protect the confidentiality of health information maintained in RHIOs, and govern the use and disclosure of such information. There is also a need for clear understanding of the remedies for breaches and the enforcement mechanisms provided under each applicable law for preventing and/or remedying such breaches.

3. The paper does not provide much detail about these requirements. These issues are also being addressed through core services and protocol development activity under SHIN-NY. The standards will need to take into account consumer access to audit information as well as breach notification.
Enforcement Process

**Definition of Issue**

4. Who will receive and investigate complaints? Who will enforce standards and requirements? What is the process for adjudicating and notifying parties as to resolution?


**Considerations**

4. DOH has certain responsibilities under current law, as does the AG. Policies need to be developed regarding where these functions reside and how will it be funded on an ongoing basis. The state could also require RHIOs to establish an ombudsman or contract with an independent entity like IPRO for this purpose.

5. Requirements based on current law and policies need to be added to contracts and participant agreements. Additional standards and enforcement mechanisms could be addressed through future legislation.
Enforcement and Protections

### Recommendations

1. RHIOs need to have internal systems designed to audit disclosures and regularly monitor to protect against unauthorized access and use.

2. RHIOs should designate staff who will oversee privacy and consent management functions.

3. RHIOs should also provide ombudsman services to consumers to handle questions and facilitate referral for complaints.

4. DOH needs to develop policies regarding RHIO and providers’ roles and responsibilities in the event of an unauthorized disclosure, disposition of complaints, consumer notification and access to information about disclosures.

5. The consent form and education process should include information about consumer rights with regard to unauthorized disclosure or use, including how to file complaints and what remedies are available.
Next Steps
Next Steps

- Work with other state agencies to clarify outstanding legal issues, such as guidance and interpretation of current law related to minors.
- Additional comments on white paper or resulting from today’s discussion can be submitted to: healthit@health.state.ny.us
- Develop standardized consent form(s)
- Issue final policy document on consent for HEAL NY Phase 5 Health IT contracts
- Continue privacy and security activities, including HISPC and statewide collaboration process throughout the year