New York Health Information Security and Privacy Collaboration

Standardized Consumer Consent Policies and Procedures
for RHIOs in New York State

December 21, 2007

Invitation to Comment:

The Health Information Security and Privacy Collaborative (HISPC) is a national initiative funded by the federal Office of the National Coordinator for Health IT and Agency for Health Research and Quality to examine how privacy and security laws impact business practices related to electronic health information exchange. The purpose of this document from the New York HISPC team is to put forth for public comment recommended policies and guidelines governing consumer consent for the exchange of personal health information in a technology-enabled health care environment facilitated by Regional Health Information Organizations (RHIOs) in New York State in order to protect privacy and strengthen security. Comments received will be reviewed and considered during the development of final policy guidance that will be issued by the New York State Department of Health. Please submit written comments utilizing the form provided on the NYS HISPC website: http://www.nyhealth.gov/technology/nyhispc/phase_iii/ to the Office of Health Information Technology Transformation by January 31, 2008 via email:

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I. Introduction and Background

Responding to growing evidence that interoperable health IT can support improvements in health care quality, affordability and outcomes, New York State is making considerable investments in transitioning its health care settings from today’s largely paper-based environment to an electronic, interconnected health care system.

On August 8, 2007, the State of New York announced an ambitious new initiative to promote interoperable health information exchange and new tools for quality and population health measurement and reporting in New York. This initiative is part of Governor Eliot Spitzer’s agenda to advance patient-centered care and enable improvements in health care quality, affordability and outcomes for each person, family and business in New York.

To launch this initiative, $105.75 million in State funding has been committed to support the implementation of health IT infrastructure. The expected benefits include:

- **Improvements in Efficiency and Effectiveness of Care:** Provide the right information to the right clinician at the right time regardless of the venue where the patient receives care.

- **Improvements in Quality of Care:** Harness the power of clinical information to support improvement in care coordination and disease management, help reorient the delivery of care around the patient and support quality-based reimbursement reform initiatives.

- **Reduction in Costs of Care:** Reduce health care costs over time by reducing the costs associated with medical errors, duplicative tests and therapies, uncoordinated and fragmented care, and preparing and transmitting data for public health and hospital reporting.

- **Improvements in Outcomes of Care:** Evaluate the effectiveness of various interventions and monitor quality outcomes.

- **Engaging New Yorkers in Their Care:** Lay the groundwork for New Yorkers to have greater access to their personal health information and communicate electronically with their physicians and designated care givers to improve quality, affordability and outcomes.

New York's investment in health IT is significant for many reasons, chief among them that it is by far the largest state investment to date in creating a public-private governance and operating model to support interoperable health information exchange and health IT tools for quality measurement and reporting and population health improvement. As exciting as this opportunity is, it comes at a time when the health IT environment is extremely dynamic. As New York charts it way through new waters, it must take into account and respond to many issues, including increased consumer
demand for health information; a newly emerging, but largely unregulated, commercial
market for health information; new clinical models for personalizing care based on
genetic and other types of information; new care delivery models, such as the medical
home, which depend on streamlined information transfer to support the continuity of
care; and new prevention and outcome-oriented reimbursement models where
information is needed to measure and account for outcomes and performance. At the
same time, concerns about the privacy and security of all types of personal information -
especially health information - abound, with daily headlines alerting the public to the
dangers of stolen laptops containing personal health information, cyber security threats,
phishing and other identity theft problems.

In pursuing its health IT investment program, New York is cognizant that its success will
not only be measured by technical, operational, financial and clinical achievements, but
similarly by the policy framework and rules governing the exchange, measurement and
reporting of personal health information and organizations ensuring the adherence to
such policies. In fact, the establishment of public trust with respect to the privacy and
security of health information is the single most important goal of New York's health IT
investment program.

In pursuing this goal, New York benefits from policy thinking developed by several
important initiatives which have addressed privacy and security, including: the Markle
Foundation's Connecting for Health initiative; the California Healthcare Foundation's
policy briefs on privacy and consumer attitudes and important policy forums; studies
advanced by such organizations as the American Health Information Management
Association (AHIMA), eHealth Initiative, Healthcare Information Management Systems
Society (HIMSS), and National Alliance for Health Information Technology (NAHIT), the
Health Information Security and Privacy Collaborative (HISPC); and the Certification
Commission on Healthcare Information Technology's (CCHIT) work on privacy and
security-related product certifications. In a very real sense, New York's investment
program builds on the collective foundation of these policy efforts and at the same time
seeks to go one step further. Because New York is setting policy in the context of live
implementations and is doing so through a statewide public-private collaborative model
it presents a unique opportunity to stress test new concepts which to date have largely
been considered in either much smaller settings, on a theoretical basis or based on
proprietary and/or narrow technological approaches. Hopefully, New York's experience
will provide all stakeholders a much richer understanding of what works and what
doesn't work, and will help to inform and shape emerging state and national policy.

Achieving Interoperability

A central strategic focus of New York State's efforts is to advance interoperability
through the development and implementation of a shared health information
infrastructure based on a community-driven model available to all providers, payers and
patients. The State health IT framework supports common policies, technical standards
and protocols, as well as regional “bottom-up” implementation approaches and care
coordination to allow local communities and regions to structure their own efforts based
on clinical and patient priorities. The framework seeks to promote innovation across the
diversity of New York’s health care delivery settings - from solo physician offices and
community health centers to large academic medical centers, nursing homes and multi-
specialty physician practices, from Manhattan to rural upstate towns - with vastly
differing market conditions and health care needs.

Interoperability is essential to realizing the expected benefit from health IT; vastly
improving the availability and use of health information to improve patient care.
Perpetuating siloed information systems that do not interconnect will significantly
impede the adoption and effective use of health IT tools. Interoperability enables
patient health information to be exchanged in real time among disparate clinicians, other
authorized entities and patients while ensuring security, privacy and other protections.
Interoperability is necessary for compiling the complete experience of a patient’s care
and ensuring it is accessible to clinicians as the patient moves through various
healthcare settings. This will support clinicians in making fact-based decisions so
medical errors and redundant tests can be reduced and care coordination improved.
Interoperability is critical to cost-effective, timely and standardized data aggregation and
reporting for quality measurement, population health improvement, biosurveillance, and
clinical research. Interoperability is also needed for patients to have access to their own
personal health information, enabling it to be portable, not tethered to a particular payer
or provider.

To ensure interoperability, the State is seeking to support the implementation of three
interrelated components of New York’s health information infrastructure –
organizational, clinical and technical. The successful implementation of New York’s
health information infrastructure must emerge from these three intertwined capabilities
in order to realize the benefit of health information with respect to improving health care
quality, reducing costs and improving outcomes for all New Yorkers. Achieving these
benefits is dependent on much more than just technology. For example, interoperability
is as much a function of trust as technology or clinical participation, and is achieved
through policy and governance.

The high-level technical framework for New York’s health information infrastructure is
comprised of three main layers and is depicted in figure 1 below1.

- **A Statewide Health Information Network for New York (SHIN-NY)** is a
  network of networks to interconnect clinicians to exchange patient information
  regardless of the venue in which the patient receives care in order to deliver the
  right care at the right time in a coordinated, patient-centered manner. The SHIN-
  NY will utilize the Internet and include common software protocols and services,
  including security tools, and will be a part of the emerging Nationwide Health
  Information Network (NHIN).

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1 For additional information, a technical discussion document published as part of the HEAL NY Phase 5 Health IT RGA is located on the DOH website: [http://www.nyhealth.gov/funding/rfa/0708160258/](http://www.nyhealth.gov/funding/rfa/0708160258/)
Clinical Informatics Services (CIS) are community-based health IT tools which aggregate, analyze, measure and report data in a standardized and valid manner for various uses, including quality and population health initiatives, available to all payers, providers and public health officials.

Information Tools (3Cs) are Electronic Health Records for Clinicians, Personal Health Records for Consumers and Community Portals for clinicians and public health officials, collectively the 3Cs, providing: (i) clinicians with information tools when and where they need them to guide medical decisions, (ii) New Yorkers with greater control over and access to their health information and (iii) Public Health Officials with the ability to survey, report and respond to population health events.

Figure 1

Framework for New York’s Health Information Infrastructure

“Cross-Sectional” Interoperability – People, Data, Systems

The Role of Regional Health Information Organizations

Underlying this infrastructure and central to its successful implementation are Regional Health Information Organizations (RHIOs). RHIOs, working with other RHIOs, governments and other organizations, must create an environment that assures
effective health information exchange both organizationally and technically through a sound governance structure. While the term RHIO is not presently defined in federal or state law, RHIOs are defined in New York State HEAL NY Phase 5 Request for Grant Applications as “a non-governmental, multi-stakeholder organization that exists as a New York State not-for-profit corporation to advance interoperable health IT in the public's interest through a transparent governance structure with an overall mission to improve health care quality and safety and reduce costs.” RHIOs are not technology organizations, do not develop software and are not proprietary regional health information exchange (HIE) networks. They are regional “exchange organizers or governors” which set policies and ensure adherence to such policies to enable the implementation of the SHIN-NY, and ensure other components of the technical infrastructure such as the CIS and EHRs are interoperable. The term health information exchange is a verb defining the act or function of mobilizing and sharing health information and the term SHIN-NY defined above is New York’s name for health information exchange. The term Health Information Service Provider (HISP) is a vendor company which develops health information exchange software and services and/or supports the implementation of such software and services.

As described more fully below in Figure 2 below, there are seven critical components of the definition of a RHIO.

**Figure 2**

**Seven Critical Components of the RHIO Definition**

- **Nature of participants**
  - Multi-stakeholder

- **Governance**
  - Transparent policy framework, 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 via SHIN-NY

- **Scope of services**
  - Security, authentication, authorization, access, auditing policies, other info policies

- **Consumer Access**
  - Provisions for ensuring consumer access to and control of data
One of the main functions of a RHIO is to act as a governor or trusted broker to establish, maintain and enforce privacy and security policies for multiple entities and for multiple purposes. Establishing a trusted broker for health information is not merely a matter of implementing a technical solution compliant with State and federal law. It requires developing consensus and trust around value-laden policy decisions, which are then translated into business procedures and eventually reflected in contractual relationships between RHIO participants.

The purpose of this paper is to provide guidance to RHIOs and their participants regarding a crucial component of interoperable health information exchange: patient consent. Patient consent must be implemented through a suite of common policies to ensure informed and trusted patient consent.

While this paper is focused on patient consent policies, it is important to emphasize that consent policies must be accompanied by a full range of privacy and security protections to earn patient trust and enable successful health information exchange. The consent policies outlined in this paper must be buttressed by additional policies for privacy and security, including authentication of provider/consumer identity, authorization for access, consumer and provider identification, transmission security, data integrity and administrative and physical security, all of which remain a priority for New York State and are encompassed in the policy framework.

It also is important to recognize that the recommendations in this paper provide a starting point for a longer discussion. While the recommended policies outlined below are often specific and directive in nature, more detailed guidance will be necessary to enable full implementation.

**Consumer Access Services - Supporting the Right of New Yorkers to Have Greater Control Over and Access to Their Personal Health Information**

As we advance health IT in New York, there is a significant opportunity to expand the way in which we have traditionally thought about consumer rights to access and use their own personal health information. Consumer access to and use of their personal health information is necessary to realize the full potential of the range of technologically-enabled care advancements. Redefining consumers’ rights, however, will require a paradigm shift in how we think about health information – supplementing the current legal structure which focuses on clinician control over the medical record and under what circumstances disclosures of such information are permissible - with a new legal structure that affirmatively provides consumers with the right to gain access to their personal health information, regardless of the source of such information, and supports the consumer’s ability to maintain such information for his or her personal use. While consumer access services and personal health records are not the focus of this paper, it is important to note that RHIOs can, and hopefully will, play an important role in enhancing consumer access to their own personal health information.
II. The Health Information Privacy and Security Collaboration (HISPC): Project Goals and Work Plan

HISPC is a national initiative funded by the federal Office of the National Coordinator for Health IT and Agency for Health Research and Quality to examine how privacy and security laws impact business practices related to electronic HIE. The stated objectives of HISPC are to:

- Preserve privacy and security protections in a manner consistent with interoperable health information exchange;
- Promote stakeholder identification of practical solutions and implementation strategies through an open and transparent consensus-building process; and
- Create a knowledge base on privacy and security issues in electronic health information exchange in states and communities that endure to inform future HIE activities.

NY HISPC Phase I

In 2006, New York State was one of 34 States and territories awarded a HISPC contract. The New York State Department of Health (NYS DOH) served as the lead agency for this project in New York State. Phase I spanned from March 2006 to April 2007 and involved a comprehensive assessment of health privacy legal and policy issues in New York State. Major findings of NY HISPC Phase I included the following:

- **Human Judgment in Information Exchange:** Information exchange currently relies heavily on human judgment and interaction to ensure security and privacy of health information.
- **From One-to-One to Many-to-Many:** Moving to a broad transfer of information to many persons or entities may require layers of sophisticated permissions and controls.
- **Informed Patient Consent:** Informed patient consent that is meaningful, tracked and monitored is a key requirement to earning patient trust in HIE.
- **Sensitive Data:** Differing regulations governing specially protected health information present challenges for staff education and compliance.
- **Appropriate Scope of Disclosure:** There is a need to more clearly define who needs to see what information and to understand how to accommodate appropriate access in an electronic environment.
- **Patient Care and Patient Privacy:** There exists a delicate balance between patient privacy and the need for information for treatment.
- **Security in an Electronic World:** There is a heightened sense of vulnerability regarding identifiable health care information in electronic form.
- **Patient Control:** There is an opportunity to create an environment that supports the right of consumers to control the use of their own personal health information.
• **Role of Regional Health Information Organizations (RHIOs):** RHIOs can play an important role in HIE by acting as a trusted broker to establish and maintain privacy and security policies.

A central finding of phase one of HISPC was that strong policies that protect the privacy and security of health information are crucial to achieving interoperable health information exchange. Current laws governing HIE and the resulting business practices were developed in the context of a paper-based health care setting where decisions on what to communicate, how and to whom are generally made on a one-to-one basis by clinicians. The current laws attempt to serve the patient’s privacy interests by restricting what can and cannot be shared and the terms on which sharing takes place. Human judgment and personal relationships play a major role, as clinicians attempt to act as the guardian of their patients’ information. Moving from a paper to an electronic health system changes the information sharing dynamic. An interoperable health system facilitates a many-to-many relationship, enabling different information technology systems and software applications to exchange information accurately, effectively, and consistently. This offers new opportunities for patient access to and control over their health care information, as well facilitating the safety, quality and efficiency of their care. However, it also demands new approaches for protecting patient privacy and security, including policies addressing the disclosure and use of health care information, and technologies that address patient identification, authentication, record location, identity management, and storage of special classes of information.

The NY HISPC Phase I advanced an “Implementation Framework” highlighted in Figure 3 below. One of the four priority solution areas was consumer consent – ensuring that consumers are able to provide informed and meaningful consent and that holders of consumer health information adhere to State and Federal privacy and security laws as they exchange health information electronically.
NY HISPC Phase II

The second phase of NY HISPC began in June 2007, with NYS DOH as the lead agency, and has focused on implementing a patient consent solution through the development of a standardized consent process. The goal of this standardized process is to promote consistency across NYS RHIOs, as exchange organizers and governors of the SHIN-NY, in obtaining consent and addressing consumer privacy concerns about electronic exchange of health information. Specifically NY HISPC Phase II project goals are to:

- Advance health information exchange via the SHIN-NY through the development of a standardized consent process implemented through and facilitated by 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 RHIO participation.

The duration of the project is from June 2007 through January 2008; the process is represented in Figure 4, below:
To engage in a statewide dialogue on consent, three stakeholder meetings were held in September and October 2007 to identify consent-related issues and gain consensus on a standardized approach. The meetings were attended by consumer advocates, health care providers, RHIO executive and clinical leadership, representatives from the City Department of Health, and others. The first meeting was dedicated to understanding the current state of RHIO policy development regarding consent in New York. The second meeting sought to elicit discussion on the key policy questions that a new consent policy for RHIOs would need to address. The key questions that provided the basis for this discussion are outlined in Figure 5 below:
At the third meeting, “straw model” recommendations were proposed and discussed. The policy guidance described in this document is the result of the discussion during those three meetings.

This document outlines a standardized consent process, related roles and responsibilities of RHIOs and participants as trusted custodians of health care information, and consumer protection safeguards required to prevent inappropriate use or disclosure of consumer health information. The policies described are still under development. As such, public comments are strongly encouraged.

II. The Need for a Standardized Consent Process for RHIOs in New York State

RHIOs across the State are struggling to define what constitutes adequate and meaningful patient consent. Broad variation in opinion exists among stakeholders as to what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy, what is best for New Yorkers and what is feasible from an implementation perspective. Standardized consent policies will help earn patient trust, provide clarity regarding compliance with New York law and ensure interoperability via the SHIN-NY enabled and governed by RHIOs.

Standard Consent Policies for RHIOs are Necessary to Ensure Complete and Consistent Health Information and Earn Patient Trust
Electronic health information exchange represents a paradigm shift in the way information is exchanged between a consumer's health care providers. In today's largely paper-based world, exchange of health information between providers generally is managed by the consumer. In order for Provider A to obtain health information from Provider B, the consumer must tell Provider A that they are receiving care by Provider B and would like their health information to be shared. The consumer in effect is the gatekeeper of a one-to-one relationship among various providers who are responsible for their care.

RHIOs usher in a new world by enabling the free flow of information, but fundamentally change the one-to-one paradigm that exists in a paper-based world. RHIOs allow providers for the first time to reach out to large networks of clinicians and providers independent of the consumer to see what information is available and use it to aid in that patient's care. This brings obvious benefits to the patient – eliminating the burden of gathering and transporting paper records, avoiding duplicative tests and procedures, and ensuring their providers have the best information available to make medical decisions and coordinate care. It also, however, takes away a measure of patient control, and for some, brings a heightened sense of vulnerability related to the transmission of identifiable health information across networks of providers in electronic form.

Because of the paradigm shift inherent in health information exchange, an essential cornerstone of New York State's health IT policy is to ensure that consumers are appropriately educated about how their health information can be shared and to provide consumers with the informed opportunity to decide whether or not they desire to have their information accessible via the SHIN-NY governed by RHIOs. If consumers are not informed of the new paradigm, they have no way of understanding to what they are consenting. Thus, from a consumer trust perspective, new consent policies which clearly define the role of RHIOs (and clinicians, providers and payers participating in RHIOs), coupled with significant provider and patient education programs, are crucial to ensuring that consumers are provided with the opportunity to make informed decisions with respect to with whom and for what purpose their personal health information is shared and used.

**RHIO Consent Standards will Facilitate Interoperability via SHIN-NY**

New York State offers a fragmented State legal and regulatory framework on consumer consent. Unlike HIPAA, New York's extensive legal requirements governing the collection, storage and exchange of health information are not organized into a single regulatory scheme. State law governing health information is spread across dozens of statutory and regulatory provisions. The result is a patchwork of requirements and exceptions that vary greatly depending on the nature of the entity, type of information involved and purpose of the disclosure. Gaps in legal/regulatory guidance result in varying interpretations and diverse consumer consent policies across RHIOs. This is apparent in the current HEAL NY Phase 1 funded projects, which have come to differing conclusions about the mandates under state law, and are implementing a wide range of patient consent policies as a result. Diverse consent policies are a barrier to
interoperability. A standardized consent process will enable consistency across RHIOs, eliminate interoperability barriers and reassure consumers that all RHIOs adhere to minimum privacy standards with regard to exchange of their health information.

**Consumer Consent is Currently Necessary under New York Law**

New York State law requires that hospitals, physicians and other health care providers and HMOs obtain patient consent before disclosing personal health information for non-emergency treatment. Unlike HIPAA, New York State law provides no exception to this requirement for treatment, payment or healthcare operations. While consent may be verbal or even implied for most types of health information, this is not the case for certain classes of specially protected health care information, including information related to HIV status, mental health and genetic testing, which require written consent. These laws reflect a desire to ensure that patients are protected from unauthorized uses of personal health information and provide both a legal and normative guidepost for developing consent policies for information exchange governed by RHIOs in New York. Thus, under any circumstances, affirmative consent from the patient to exchange health information via SHIN-NY governed by a RHIO is required under existing state law for non-emergency treatment.

**State and Federal Law Provide an Insufficient Framework for the Regulation of RHIOs**

It is crucial that the state ensure adequate policies and standards are in place to protect the integrity of RHIO activities and the privacy of the public. HIPAA applies only to “covered entities,” which include certain health care providers, health plans and health care clearinghouses. RHIOs are not health care providers, health plans or clearinghouses. Accordingly, at the present time, it does not appear that any of the RHIOs will be covered entities. Under HIPAA, a business associate is an organization that assists a covered entity in performing certain health-related or administrative functions, and receives, creates or maintains protected health information in connection with these activities. To date, most if not all RHIOs in New York have been structured as business associates of RHIO participants under two basic models:

- **“Peer-to-Peer” Model**: The RHIO supports technology that enables providers to exchange data directly with one another. The RHIO may facilitate access to each provider’s data to ensure the proper functioning of the system. There is no central data repository (CDR) governed by the RHIO. Under this model, the RHIO *is* a business associate of each provider.

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2 A health care clearinghouse is an entity that converts electronic HIPAA-covered transactions (i.e., claims processing and other transactions between health care providers and health plans) from non-standard to standard formats (or vice versa). By definition, RHIOs in New York are not performing such data conversion activities.
• **“Custodial CDR” Model:** The RHIO supports a CDR in which each provider’s data is stored. Each provider continues to own its data. The RHIO holds the data on behalf of each provider as a custodian, and has no ownership rights in the data. If a provider leaves the RHIO, the provider’s data must be returned or destroyed. Under this model, the RHIO is a business associate of each provider.

A potential third model for health information exchange is an “Owner CDR” Model. Under this model, the RHIO (or other entity facilitating health information exchange) would not be a business associate of the participants in the data exchange. Instead, the RHIO would own the data in its care. To implement this model, each provider would be required by federal law to obtain a HIPAA authorization from each patient permitting the transfer of his or her protected health information to the RHIO or other entity. The HIPAA authorization itself would be required to state that the RHIO is not a covered entity and therefore not required to comply with HIPAA.

It is not prudent to mandate that all SHIN-NY and CIS pilot projects be structured in a manner that qualifies the RHIO as well as vendors and other technology service offerings as a business associate of the participating providers. Such a mandate may stifle innovation, such as new business models designed to create integrated data sets comprised of data contributed by multiple providers to support disease management and other quality interventions. At the same time, however, permitting the aggregation of substantial amounts of health information in an entity that is outside the scope of state or federal privacy regulation raises significant privacy and consumer protection concerns, even if data is transmitted to the entity pursuant to patients’ HIPAA authorization.

To address these competing considerations, the State should avoid dictating the manner in which RHIOs fit within the HIPAA regulatory scheme, and instead, create a cohesive State regulatory framework that applies directly to RHIOs. This framework would include relevant aspects of HIPAA as a floor and other privacy laws to establish a set of requirements governing the use and disclosure of information, security safeguards, patient access to data and other matters.

### III. Key Principles and Stakeholder Priorities

The recommended policies for obtaining consumer consent to exchange personal health information via the SHIN-NY governed by RHIOs were guided by several key principles, summarized in Figure 6.
These principles outline the core policy aspirations and practical considerations necessary to implement interoperable health information exchange. Buy-in from multiple stakeholder groups is important, and throughout the course of the public meetings it was clear that stakeholders approach RHIOs with a host of pressing needs.

- **Consumers:** Consumers seek assurance that they have a meaningful level of control over who is able to access their protected health information. They want choices and they want to have enough information in the consent process to make that choice meaningful and knowing. Consumers want to know that those who have access to their information use it to improve the delivery and quality of their care, and do not use it in a way that could cause them embarrassment or harm. Consumers are particularly concerned that their sensitive health information is protected and only viewed by authorized individuals for whom they enable access.

- **Clinicians:** Clinicians want to ensure clinical effectiveness and high quality care. They want access to a consumer’s complete medical record at the point of care to enable the provision of consistent, high quality and safe medical care. They are equally concerned that consent requirements do not impose heavy burdens on them and their staff, especially for doctors in small practice settings.

- **Provider Organizations:** Provider organizations want assurance that additional consent requirements do not impose heavy administrative, technical and/or financial burdens on their organization and its resources. Such institutions often already have internal information systems and want to ensure that new systems can be implemented in harmony with existing work flow and other requirements related to internal systems.
• **Payers**: Payers increasingly are taking an active role in helping support improvements in health outcomes for their members by employing personal health records and disease management initiatives. With this in mind, payers want access to clinical information on their members for the purpose of delivering care management services, improving quality and reducing cost. Payers also note that they are being asked to contribute to the cost of RHIOs and to make claims data available to RHIO participants, and they want to know that these investments will realize a benefit.

• **RHIO Executives**: RHIO executives want to ensure that new consent policies and procedures give RHIOs operational flexibility and support an evolving landscape as they embark on implementing their health information exchange. They are concerned that new consent policies and procedures will be difficult to implement, sustain and monitor, and that they will place burdens on providers that may reduce their participation. RHIO executives also are concerned about how to fund mandates that are different from the standards they have begun to implement. With limited resources, extremely small central staffs and with guidance coming on the eve of or even just after information has begun to flow, RHIO executives want to know that they will have the funding necessary to support implementation of new and evolving standards.

• **Government**: Policymakers are charged with advancing health IT to support improvements in health care quality, affordability and outcomes. Through a statewide, multi-stakeholder process, health IT strategies are formulated in the public’s interest and facilitate a dynamic, bi-directional information infrastructure to support quality improvement interventions, public health reporting and biosurveillance activities. Protecting the privacy of individuals and earning and maintaining their trust is a top priority of policymakers; understanding that success will be not realized without broad-based support from patients, clinicians, providers, payers and other stakeholders in the healthcare system.

### IV. Recommendations

The following policies and practices seek to provide specific guidance to RHIOs of sound patient-centered public policy while at the same time being operationally and financially feasible. Several areas, however, have been identified in which more process and thought is necessary before more detailed recommendations can be put forth. In those instances, the report recommends further action through a statewide collaboration process facilitated by the New York’s public private partnership convened by the NY eHealth Collaborative (NYeC) (described further in Section VIII).

The recommendations are summarized in Figure 7 and described in more detail below:
Recommended Policies and Standards for Consumer Consent to Exchange Information via SHIN-NY governed by RHIOs

1) **Scope of Governed Activities:**
The new consent rules apply statewide to interoperable health information exchange of patient identifiable health information via SHIN-NY governed by RHIOs and their participants.

2) **Affirmative Consent:**
Each provider organization and payer organization participating in a RHIO must obtain an affirmative consent from the consumer that specifically references the RHIO prior to accessing her/his personal health information.

3) **Up-Loading Data:**
Health care providers may "upload" patient information to a RHIO without patient consent.

4) **Uses of Health Information:**
Permissible uses of health information fall into two categories, each requiring different types of consent.

5) **Sensitive Health Information:**
A single consent may be obtained to exchange all health information, including all specially protected health information.

6) **Consent Form:**
RHIOs must use a State-approved consent form.

7) **Durability and Revocability:**
RHIO consents are both durable and revocable.

8) **Consumer Engagement and Access:**
RHIOs must comply with consumer education, engagement and access standards.

9) **Audits and Transparency:**
RHIOs must conduct audits at least annually; inform consumers promptly of any breaches and make audit trails available upon request. It is anticipated that online tools and paper-based reports will be utilized.

10) **Benefits and Penalties:**
To be eligible for State funding through HEAL and other initiatives, and to receive Medicaid data, RHIOs must adhere to consent policies.

11) **Enforcement:**
Consent standards initially will be enforced through contractual relationships between RHIOs and New York State, and should migrate towards requirements for an accreditation process.
**Scope of Governed Activities:** The new consent rules apply statewide to health information exchange of personal health information via the SHIN-NY governed by RHIOs and their participants.

The scope of activities that the following policies seek to govern includes all interoperable health information exchange conducted through SHIN-NY and governed by RHIOs. RHIOs are important because the definition of interoperability includes much more than technical interoperability of information systems; it is people and policies or organizational interoperability, also.

Health information exchanges, like SHIN-NY, use the term liquidity to express the level of interoperability or rate of flow of assets through the exchange. Exchanges are characterized as very liquid when almost all uses succeed (e.g., finding clinical information about a patient to inform medical decisions; receiving a drug-drug interaction alert). Conversely, in an illiquid exchange a large number of uses may fail (e.g. not finding current and/or complete medication profiles for patients).

A high level of liquidity for the health information flowing through SHIN-NY is essential. The key to generating liquidity in any exchange is the belief on the part of stakeholders that uses of the exchange will succeed and be beneficial and that, in rare cases of problems, the stakeholders will be protected and problems solved. This is as much a function of trust as technology or clinical participation, and is achieved through policy and governance, which is the main purpose of a RHIO. Thus, policies that govern the SHIN-NY must be implemented through the RHIO, and the policy recommendations outlined in this document are applicable to all RHIOs, or other similar entities governing health information exchange.

RHIOs must ensure the health information service providers with whom they contract for health information exchange software and services and the participants of the RHIO comply with the minimum protocols, standards, and services of the new consent policies and procedures. All statewide health information exchange enabled by a RHIO must comply with RHIO protocols and standards related to consent, with limited exceptions described below.

One exception relates to “one-to-one” electronic health information exchange. “One-to-one” health information exchange taking place through a RHIO is not subject to new consent policies. One-to-one exchange is best described as a request by a treating clinician to receive information from or send information to an identified source (i.e. either another clinician or an ancillary service provider.) Common examples include physician referrals, a discharge summary being sent by a treating hospital to the referring physician, or the delivery of lab results to the clinician who ordered the test. One-to-one exchanges utilize technology to transfer information in a way that mirrors paper-based exchange, in essence, simply replacing the facsimile machine with email. Each one-to-one exchange is understood and predictable to the patient, and limited in scope to the two exchanging providers.
RHIOs may include one-to-one exchange services among their offerings. So long as the RHIO has the capacity to separate this exchange – including policies and tools that enable the types of exchanges within the RHIO to be readily distinguishable – RHIOs need not apply the new consent policies to one-to-one components of the exchange. Obviously, consent requirements in existing law applicable to any one-to-one exchange remain in force.

The “one-to-one” exception is important to avoid significant unintended consequences that could impact a range of electronic health information exchange activities that are adequately regulated and do not constitute community-wide or statewide health information exchange. However, further guidance is required to clearly distinguish the line between “one-to-one” and community-wide/statewide exchange. More deliberation and guidance is necessary regarding the boundaries of “one-to-one” exchange to ensure that it is enforceable and effective, and does not disrupt existing techniques for a clinician and provider to access information he/she ordered for a patient.

It also is important to note that to the extent public health reporting does not require consumer consent under New York law, consent requirements related to RHIOs do not apply to information exchange related to such reporting. However, public health reporting has been recognized as a high priority for RHIOs in New York and RHIOs are encouraged to integrate public health reporting into consumer education efforts.

Furthermore, the new consent policies and procedures for RHIOs apply only to identifiable data. According to HIPAA, “de-identified health information neither identifies nor provides a reasonable basis to identify an individual.” While greater clarity is required regarding consent policies and procedures for de-identified data exchanged through a RHIO for quality and population health measurement and reporting, clinical research, among other purposes, this requires further deliberation that is beyond the scope of this initiative and should be further developed through the statewide collaboration process and approved by the State.

Finally, minimum technical 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.

**Affirmative Consent:** Each provider organization and payer organization participating in a RHIO must obtain an affirmative consent from the consumer that specifically references the RHIO prior to accessing her/his personal health information.

Affirmative consent must be obtained by each provider and payer organization before accessing health information via the SHIN-NY governed through the RHIO. Consent to providers may be done at a provider or organizational level (e.g. medical practice, hospital) and need not be at the individual clinician level. Once a provider obtains patient consent, it may access the information of all other participating providers unless the RHIO has voluntarily established additional restrictions on disclosures as indicated below. It is required that providers and payers each obtain consent prior to accessing
information; a one time general consent which provides multiple organizations with simultaneous consent will not be permissible for reasons discussed in Section VII.

Providers and payers may, at their discretion, also seek consent prior to disclosure of personal health information, but are not required to do so. This option is likely to be of special interest to providers of particularly sensitive health services (e.g. family planning and abortion service providers) because it would limit the access of other health care providers (who had obtained their own consents) to this sensitive information unless the patient expressly authorized the provider of the sensitive services to make the information available.

Consumers must be able to prevent any or all provider and payer organizations from accessing their personal health information via SHIN-NY governed by a RHIO without being refused treatment or coverage.

In an emergency situation in which the consumer is unconscious or otherwise unable to give or withhold consent, and the treating clinician determines that information that may be held by the RHIO may be material to treatment, and the consumer has not previously withheld consent for the provider organization to access his/her information, the RHIO may allow the physician to access the consumer's information 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.

As indicated above, the transfer of data to an “Owner CDR” model would require a HIPAA authorization in addition to meeting state standards related to affirmative consent.

**Up-Loading Data:** Health care providers may upload patient information to the SHIN-NY governed by a RHIO without patient consent.

Health care providers may upload patient information without patient consent to a CDR maintained by a RHIO if the RHIO is serving as the provider’s business associate and the RHIO does not make the information accessible to other RHIO participants until patient consent is obtained. Health care providers routinely enter into data storage and management arrangements with electronic medical record hosting vendors, outsourced data centers and other technology companies. Indeed, many facets of a provider’s routine operations may be carried out by independent contractors who have access to identifiable patient information, and this occurs without patient consent.

To date, New York regulatory authorities have not interpreted the State’s existing medical privacy laws as requiring patient consent for the storage or management of data by technology vendors acting on behalf of health care providers. If a vendor holds patient data solely as a custodian of the provider and does not make the data available to other entities, the storage arrangement is not treated as a “disclosure” to a third party requiring consent under New York law. Accordingly, existing New York law does not require providers to obtain patient consent to upload information to a RHIO as long as
the RHIO does not make the information accessible to other entities without patient consent. No change in New York law is required in this area.

This approach regarding patient consent is appropriate for three primary reasons. First, information uploaded to a RHIO will not be viewed by other entities, and therefore patient privacy will not be compromised. Second, the information held by the RHIO will be subject to the RHIO’s obligations under its business associate agreements, which track HIPAA requirements. Third, uploading information in this manner will expedite providers’ access once patient consent is obtained or in an emergency thereby making important clinical information available at the point of care.

It is worth noting that the concept of “uploading” data – where information is held on behalf of a provider or payer by a business associate – is not possible where the RHIO is acting as an Owner CDR. RHIOs operating under an Owner-CDR model would be required to obtain a HIPAA authorization and affirmative consent before any transfer of data would be permissible.

**Uses of Health Information**: Permissible uses of health information fall into two categories, each requiring different standards of consent.

Consent policies will be determined and applied according to the use of the information. There are two levels of permissible uses and therefore two different standards of consent. Level 1 Uses include uses that are likely to be expected by the consumer and bring the consumer direct personal benefit, including information exchange for the purposes of treatment, quality improvement and care management. A description of Level 1 Uses follows.

- **Treatment**: Treatment is defined as the provision, coordination, or management of health care and related services among health care providers or by a health care provider, and may include providers sharing information with a third party. Consultation between health care providers regarding a patient; and the referral of a patient from one health care provider to another also are included within the definition of treatment.

- **Quality Improvement and Disease Management**: These activities include conducting quality measurement, assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, population-based activities relating to improving health or reducing health care costs, clinical decisions support and evidence-based clinical protocol development, case management and care coordination, contacting of healthcare providers and patients with information about treatment alternatives, and related functions.

Any entity accessing information must have had a relationship with the individual who is the subject of the information and the information must pertain to such relationship. In
addition, disclosure of information for quality improvement purposes must be restricted to the “minimum necessary,” consistent with requirements under HIPAA.

Level 2 Uses are less likely to be anticipated by the consumer or to bring direct personal benefit. Level 2 Uses include research, marketing and other uses that are not Level 1 or prohibited. Descriptions of Level 2 Uses include:

- **Research**: Research means a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge, including clinical trials.

- **Marketing**: Marketing means any communication about a product or service that encourages recipients to purchase or use the product or service; or an arrangement whereby a RHIO participant discloses consumer health information to another entity, 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.

Standards for obtaining consent 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.

Certain uses of information exchanged by or received from RHIO participants will be prohibited. Prohibited uses include underwriting, discrimination and other such uses as may be designated by the statewide collaboration process and approved by the State.

Finally, RHIOs also must have limitations on re-use and disclosure that provide protections identical to those provided under HIPAA.

**Sensitive Health Information**: A single consent may be obtained to exchange all health information, including specially protected health information.

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. An exception to this rule is information from designated substance abuse providers that are subject to current Federal law. Further guidance related to consent to exchange information from federally qualified substance abuse providers through a RHIO currently is being sought through the national HISPC process. Pending that guidance, standards on the exchange of substance abuse information is expected to mirror other specially protected health information.³

RHIOs and their participants may, but are not required to, offer consumers the ability to screen certain types of sensitive information from exchange through the RHIO.

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³ The Substance Abuse and Mental Health Service Agency (SAMHSA) intends to provide clarification to federal law so that alcohol and substance abuse information can be included in health information exchange efforts with affirmative patient consent.
Clinicians must have the discretion, in consultation with their patients, to withhold information from the health information exchange.

To ensure that consumers have knowledge of which providers are making the consumer’s health information available through the RHIO, consumers must be informed of the RHIO participants at the time of consent. If the RHIO enters into contractual arrangements to share data with other RHIOs, consumers must be informed of which RHIOs they share such information. Consumers also must be informed that RHIO participants change over time and be given instructions on how to learn about changes in RHIO participants. RHIOs must make available to consumers real time information on which entities are participating in the exchange.

**Consent Form:** RHIOs must use a State-approved consent form.

A standardized consent form will be developed through the statewide collaboration process and approved by the State for use by RHIOs. The State Department of Health, at its discretion, may approve customized forms created by a RHIO so long as the form complies with the minimum standards incorporated in the State’s form.

The standardized consent form required for Level 1 Uses must include the following:

- A description of the intended uses;
- What information is being exchanged including specific reference to HIV, mental health and genetic information;
- The consumer’s right to revoke consent; and
- Information about who is participating in the exchange including through data sharing relationships with other RHIOs and how to stay informed about participants in real time.

The standardized consent form required for Level 2 Uses must include all of the above plus information about:

- The specific entities with whom information will be disclosed;
- For what specific purpose information is being exchanged;
- Whether information is subject to re-disclosure;
- Whether the RHIO or its participants will benefit financially from exchange of the data; and
- The expiration date of the consent.

Certain Level 2 Uses may require an authorization under HIPAA. As discussed above, all exchange under the Owner CDR model also would require a HIPAA authorization. It may be possible to combine the HIPAA authorization and the standardized state consent form into a single document.
**Durability and Revocability:** RHIO consents are both durable and revocable.

Consent for Level 1 uses are not time-limited but can be revoked at any time. Consent for Level 2 Uses must be time-limited for a period specified in the notice. Revocation of consent prevents a RHIO participant from accessing information through the RHIO in the future. However, any data that has been accessed by the participant in the past will remain part of the participants’ records.

**Consumer Engagement and Access:** RHIOs must comply with consumer education, engagement and access standards.

New York State will facilitate a consumer education initiative. New York is currently working in partnership with NYeC and consumer representatives to craft a public education and consumer engagement initiative. The initiative will include the development of consumer-centric materials geared towards ensuring consumers understand how SHIN-NY and RHIOs change the way their health care information is accessed as well as the potential benefits and risks. In addition, the New York State Department of Health is seeking to participate in a Multi-state Consumer Education Collaborative in the next stage of the federal HISPC initiative, with a state specific project on development of educational materials around the consent process.

Robust consumer education standards will be developed and approved by the State to ensure that consumers are aware of what they are consenting to and to whom their personal health information is available. RHIOs must conform to consumer education program standards developed by a statewide collaboration process and approved by the 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.

RHIOs must have policies in place related to consumers’ access to their own health information through the RHIO and must inform consumers of those policies through their education efforts. Both the federal privacy regulation and state law mandate that certain covered entities and health care providers provide people with access to their own health data. However, the law does not require the information be disclosed in electronic form, even if such capacity exists. People often experience cost and bureaucratic hurdles in getting copies of their health information, particularly if an acute or chronic illness is involved, or if there are multiple providers. Thus, RHIOs pose an opportunity for consumers to have one-stop-shopping, requesting their dispersed information through a single electronic portal. At this early stage of development, RHIOs should set their own policies as to the form, time period and cost for responding to such requests. However, in the future, guidelines as to consumer access should be developed as part of the statewide collaboration process.
It is worth noting that as the market for consumer-driven health information products grows, RHIOs will have increasing opportunities to work with third parties to facilitate consumer access to their personal health information. A number of companies are planning to offer software applications and services that will give consumers the ability to organize and keep their personal health information in electronic form as a Personal Health Record. Under current law, it is permissible for RHIOs to provide information to such companies, provided such information is obtained through a valid state law consent and, where necessary, HIPAA authorization. However, there is currently no state regulatory framework for regulating third parties who gain access to information through a HIPAA authorization and state law consent representing a gap in current law. Use of such information therefore would be governed by (i) the terms of the consent; (ii) the RHIO’s contract with the third party and (iii) the privacy policies of the third parties. While beyond the scope of this paper, it is crucial that further consideration be given and policy guidance developed to help RHIOs ensure protection of consumer interests while facilitating consumer access to and control of their personal health information through such third party arrangements. In the interim, the policies in this paper can be looked to for guidance. Until such policy guidance is developed, proposals involving state funds will be reviewed on a case-by-case basis to ensure adequate protection of consumer interest.

Audits and Transparency: RHIOs must conduct audits at least annually, inform consumers promptly of any breach and make audit trails available upon request.

RHIOs (or a third party designated by the RHIO) must conduct periodic audits no less than annually. Audit reports, including identification of breaches, must be submitted regularly to the Board, but also no less than annually. RHIO participants are required to inform the consumer of breach (the consumer’s identifiable information is reasonably believed to have been acquired by an unauthorized person) of the consumer’s health information promptly upon detection. RHIOs and participants must make available to the consumer upon request an audit trail of the consumer’s health information accessed through the RHIO.

Benefits and Penalties: To be eligible for State funding through HEAL and other initiatives, and to receive Medicaid data, RHIOs must adhere to minimum consent policies and standards.

Recognizing the complexity and effort on the part of RHIOs and their participants in implementing a standardized consent process, compliance with new consent policies and procedures will be tied to significant and meaningful benefits for RHIOs. In the immediate term, compliance with standardized consent policies will be a condition of eligibility for access to Medicaid data and HEAL funds. Penalties of not complying with consent policies will include loss of benefits described above.

Enforcement: Consent standards initially will be enforced through contractual relationships between RHIOs and New York State, and should migrate towards accreditation.
It is well understood that RHIOs are in the early stages of building their organizational infrastructures and that much will be learned in the next several years with respect to different models for ensuring consumer participation in health information exchange. In the short term, RHIOs will be expected to implement the consent provisions adopted by the State as part of their contractual agreements with the State. Such provisions will be considered in light of the specific needs of each project allowing adequate time to implement the consent procedures and, if necessary, transition from other models deployed. Contractual agreements with the State will also take into account that consent policies and procedures can be expected to evolve over the next few years through a statewide collaboration process.

In the longer term, it can be expected that RHIOs will be subject to a broader State regulatory framework which may include accreditation of RHIO governance, privacy and security policies and other policies viewed as critical to the RHIO’s role in establishing public trust as to the collection, storage and use of personal health information, protection from liability under certain circumstances and defined penalties for breach of RHIO obligations.

For public trust to develop there must be an open and transparent process for establishing and monitoring RHIOs or similar entities charged with ensuring the privacy and security of health information. Accreditation is the best vehicle for ensuring accountability. An independent accreditation entity would include public and private representation, ensuring input from consumers and other industry stakeholders. Ideally, the accrediting entity would function as a public-private partnership, so that compliance with accreditation criteria would confer benefits and penalties by State and Federal officials. Additionally accreditation criteria would evolve as the health information exchange movement matures allowing state and federal governments to recognize the process accordingly instead of dictating one that is subject to continuous evolution for the next several years. An accreditation process for RHIOs as entities governing health information exchange would also mitigate state-by-state health information exchange regulation perpetuating and exacerbating the current patch work of state laws severely limiting multi-state and nationwide health information exchange.

V. Discussion of Policy Considerations

Enables consumers to make informed decisions regarding their personal health information and promotes trust.

While national surveys reveal that consumers generally support electronic collection, storage and exchange of health information, concerns about the privacy and security of their health information remain pervasive. An affirmative consent prior to accessing personal health information is critical to earn consumer trust in RHIOs and to preserve

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consumer trust in their healthcare providers. The policies advanced in this document seek to balance the need to encourage providers and payers to build the technical infrastructure and capacity to promote greater information sharing, while at the same time maintaining the consumers' ultimate rights to determine who has access to their personal health information.

Promotes provider access to complete patient records for clinical effectiveness and tools to support quality improvements and cost reduction.

Providers who have a full understanding of the patient's relevant medical history are best equipped to provide high quality, cost effective care. Throughout the HISPC process, stakeholders have struggled with how best to ensure clinicians have the best available information to consistently and comprehensively treat their patients, without encouraging "self-protective" behaviors among patients concerned about the exchange of particularly sensitive health information. Patients who are concerned that information related to their healthcare could subject them to discrimination or embarrassment may avoid treatment or attempt to mask information in the care relationship. This has led some to suggest that certain types of information should be excluded from the exchange, or subject to higher standards of consent. Others have noted that to exclude sensitive health information would undermine the benefits of health information exchange for the very populations who need it most.

Ultimately, the recommendations created a high standard for all health information. First, the consent form specifies consent to exchange all information, including HIV, mental health and genetic information. Second, by requiring that each provider organization and payer organization obtain consent to access the patients' health care information, consumers are given the ability to exclude certain providers from accessing health information through the exchange. Thus, patients can ensure that only trusted entities have access to their information. Third, providers retain the discretion to withhold information from the exchange. Some types of specialized providers in particularly sensitive areas of practice, such as a genetics clinic, may choose to not disclose any patient information from their practice and instead use the exchange only to access data. In addition, clinicians will be given the discretion to consult with their patients and make the best decisions for their care. Some providers may choose to obtain consumer consent prior to uploading the consumer's data to the RHIO. Finally, the recommendations prohibit participants from conditioning payment or treatment on execution of the consent, ensuring that consents are voluntary, not coerced.

At the same time, the policy helps ensure that clinicians have access to a complete medical record to treat patients in their care, and does not require RHIOs to facilitate filtering of patient data.

Supports payer access for the purposes of care management

The recommendations seek to facilitate broad use of health information for uses that promote good medical care and treatment, whether such uses are part of provider or payer directed initiatives. Consumer always have the right to limit access of any
organization to their personal health information, but with their consent, information is
freely transferable to support better medical decision making and a broad range of care
management and quality programs.

There are differing views as to whether third-party payers should have the same level of
access to information exchanged through RHIOs as health care providers. Advocates
of payer access argue that payers perform important case management and quality
improvement functions, and that payer participation in the RHIO will improve patient
care. It is also noted that payers are actual or potential financial supporters of many
RHIOs, but are unlikely to lend such support if they are subject to onerous access
limitations. Critics of payer access argue, in turn, that it is not within the reasonable
expectation of patients that a consent they sign at a health care provider site will
facilitate their insurer’s access to information. There is a concern that many patients will
feel misled when they learn their insurer has gained access to their information, without
regard to the actual language contained in the consent form. There is also suspicion
that payers may use information obtained through RHIOs against patients for
underwriting and other purposes unrelated to the delivery of medical care.

Imposing substantial restrictions on payer access to RHIO information is likely to
impede needed financial support for certain RHIOs and undermine legitimate payer-
based quality improvement activities. However, permitting payers to access information
pursuant to patient consent obtained by providers poses an unacceptable risk of
consumer confusion and dissatisfaction.

To address these competing concerns, it is recommended that payers be permitted to
access RHIO information only if the payer has obtained its own consent from the patient
that specifically references the RHIO. A payer should not be able to rely on a RHIO
consent obtained by a provider or a general consent obtained by the payer that does
not reference the RHIO. In addition, the payer’s consent should permit use of the
information only for care management and quality improvement intended to benefit the
patient, not medical underwriting and similar practices. Finally, to ensure that the
patient’s consent is voluntary, payers should not be permitted to condition enrollment or
benefits on the patient’s willingness to sign the consent.

Promotes uniformity in privacy policies to be adopted and implemented by RHIOs
across New York State to achieve interoperability via SHIN-NY

One of the main goals of the policies advanced in this document is to promote uniform
adoption of privacy policies across RHIOs in New York State; thereby ensuring patient
information is truly portable through chain of trust agreements among multiple RHIO
networks comprising the SHIN-NY so that patient care improvements can be realized.
Uniform privacy policy adoption is critical to interoperability of information via the SHIN-
NY and ensuring that consumers gain a common understanding of what it means to
consent to their information being accessed through a RHIO.

In building consensus around a uniform policy, it was necessary to make some hard
choices as well as choices that are inconsistent with some current practices of emerging
RHIO organizations. For example, the recommendations do not permit a one time, multiple organization consent policy, but instead requires each provider organization and payer organization to obtain consent to access information. Having the accessing clinician or organization obtain consent will engage the organization in educating consumers about the consent process. It also will allow consumers to connect the consent decision to the specific entity to which the consumer is granting access - whether it is at the office of their primary care physician, their local hospital, a specialty care provider or at the point in time when they elect to select their health insurance carrier.

Recognizes early state of development of RHIO business models and permits flexibility in how market develops

The recommendations take into account the early stage of many RHIO technical and business models and takes great care to promote uniform adoption of consent policies, without limiting or specifying the manner in which the policies are adopted by RHIOs. The policies are technology neutral, so that they are adaptable to multiple technology approaches, and will allow RHIOs to adapt to changes in the healthcare industry such as evolving models of care, the emergence of new clinical practice models; increasing emphasis on home care and community-based services, new payment models, quality interventions and increasing consumerism and technological advances.

It is understood that some RHIOs in New York are currently implementing privacy and patient consent policies that do not align with the state’s strategy regarding the SHIN-NY and corresponding policy framework. These RHIOs therefore may need to modify or adapt their privacy and consent policies based on the conclusion of this project and policy guidance issued by the Department of Health. If applicable, the Department of Health will work with individual projects to develop reasonable timelines and approaches for implementing these changes.

Streamlines and clarifies process for obtaining patient consent to access and disclose health information

The recommended policies make clear that RHIOs may upload data without patient consent to a CDR (central or distributed distribution model), thereby clearing the way for RHIOs and their payer and provider partners to build a technical infrastructure that can support real time data exchange. One of the main reasons for providing consumers with protection and control over the health information through a consent to access requirement, rather than a consent to disclose requirement, is because it is believed that the latter would impose very real obstacles in the ability to build a system that supports real time data exchange. Further, the policies abandon the “opt-in” versus “opt-out” framework for a more holistic approach.

Limits additional requirements on provider organizations

Understandably, there is significant concern among physicians and hospitals that new rules not place burdensome obligations or unfunded mandates on clinicians whose
main focus is on providing treatment based on the best available information about the
patient. By requiring a simple access consent on a State approved form that covers all
types of health information, the recommended policies adopt a straightforward and
easily implementable solution for provider organizations that mirrors the process already
in place.

Some have argued that a better approach would be not to require any affirmative
consent at all, but to allow patients to “opt-out” of the system if they so choose. But this
approach is not workable under current New York State laws which require affirmative
consent. It also is inconsistent with New York’s longstanding protection of consumer’s
right to control who has access to their health information. Significantly, the policy
recommendations are careful to avoid unintended consequences. This is done by
focusing the consent rules to health information exchange via SHIN-NY governed by
RHIOs, and by making it clear that the rules do not apply to one-to-one exchanges.
While the RHIO might use technology to facilitate the delivery of the physician ordered
results, the nature of that exchange is no different than transmission by a facsimile
machine. It is predictable and foreseeable to the patient, and does not expose the
patient to any greater risk of disclosure.

VI. Next Steps

After review of comments submitted in response to this document, the State
Department of Health will issue final policy guidance and take action to include its
recommendations in all future contracts with RHIOs in New York State and inform future
legislative and regulatory proposals. The contract provisions will require RHIOs to:

• Adopt privacy policies and procedures consistent with State recommendations;
• Use the standardized RHIO consent form approved by New York State to access
identifiable health information via the SHIN-NY governed by a RHIO; and
• Participate in a consumer education program initiative launched through the
statewide collaboration process to support the Privacy Policies and Procedures.

It is also recognized that further work and ongoing guidance is necessary to ensure the
successful implementation of these standards. The recommended standards seek to
provide specific, implementable policy guidance to RHIOs. Several areas have been
identified in which more process and thought is necessary before specific
recommendations can be put forth. In those instances, further action through a
statewide collaboration process is recommended.

New York State is implementing a statewide collaboration process to advance a
governance and policy framework for health information technology initiatives across
the State. The purpose of the statewide collaboration process is to:
• Providing a convening vehicle for the State and the health care community to collaborate on key areas of New York’s health information technology agenda, starting with HEAL NY Health IT projects;
• Providing a forum to discuss and collaborate on health IT policy priorities; and
• Coordinating and harmonizing the implementation of regional HIE and quality and population health IT tools.

The New York eHealth Collaborative (NYeC), a NYS not-for-profit corporation is facilitating the state level collaboration process and providing technical assistance to HEAL grantees. The Department of Health is participating in the collaboration process as a public-private partnership. NYeC’s mission is to improve health care quality and efficiency through health IT and is comprised of health care leaders across the State, including physicians, hospitals, health plans, public health officials, safety net providers, employers, consumer and health care advocates, quality and regional health information organizations, and includes participation by health information service providers (vendors) and health care associations.

Among the issues that will require attention through a statewide collaboration process are:

• Further definition of “one-to-one” health information exchange;
• Development of consumer education materials and campaign;
• Develop policy guidance to help ensure protection of consumer interests while facilitating consumer access to and control of their personal health information;
• Consent policies and procedures for use of de-identified data exchanged through RHIOs, focusing on ensuring adequate protections against reidentification;
• Consent policies and procedures relating to minors; and
• Consent policies and procedures relating to information obtained from federally qualified alcohol and substance abuse facilities.

VII. Acknowledgements

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In the last six months, NY HISPC, as part of Phase II, held three stakeholder meetings to build consensus around a patient consent solution. The meetings were well attended with participation from diverse stakeholders across the state, including providers, payers, employers, business leaders, health IT leaders, public health, consumer and health advocacy representatives, and government, among others.
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Linda Erlanger            Affinity Health Plan
Lori Evans                NYS DOH
James Figge               NYS DOH
Ellen M. Flink            NYS DOH
Christina Galanis         Southern Tier Health Link
Jim Garnham               GRIPA
Luke Garvey               VNSNY
Jeff Gilbert              PPFA
Walter Ginter             NAMA
Janlori Goldman  Columbia College  
Stacey Goldston  North Shore LIJ Health System  
Caroline Greene  Planned Parenthood of NYC  
Pat Hale  Adirondack Regional Community Health  
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John Hatchett  Cicatelli Associates  
James Heiman  LIPIX RHIO  
Mary Ellen Hennessy  NYS DOH  
Martin Hickey  Excellus  
Judy Iversen  Visiting Nurse - New York  
Natasha Johnson  NYCLIX, Inc.  
Lee Jones  Med Allies  
Jonathan Karmel  NYS DOH  
Edward Kemer  Rochester RHIO  
Irene Koch  Maimonides Medical Center  
Dianne Koval  Med Allies  
Ted Kremer  Rochester RHIO  
Karen LeBlanc  Seton Health  
Matthew Lesieur  NY AIDS Coalition  
Art Levin  Center for Medical Consumers  
Michelle Lopez  CHNNYC  
Wilfredo Lopez  Consultant  
Alex Low  United Hospital Fund  
Gloria Maki  AIDS Institute Consultant  
Anne Maltz  Herrick Feinstein  
Vesna Marincek  NYS OMH  
Al Marino  Queens Consortium  
Glenn Martin  Queens Health Network  
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Eric Nielsen  GRIPA  
Heather O'Connor  ARCHIE  
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Ingrid Pessa  GHI  
Peter Poleto  HANYS  
Dan Porreca  Health Link - Western NY  
Ronald Pucherelli  Medical Society of New York  
Jean Quarrer  NYS DOH  
Tom Quinn  Community General Hospital  
Barbara Radin  Bronx RHIO  
Lygeia Ricciardi  Columbia College  
Laura Rosas  NYS Dept. of Health & Mental Hygiene  
Alice Rothbaum  NYS DOH OH & Mental Hygiene  
Beth Roxland  NYS Task Force on Life and the Law  
Jerry Salkowe  MVP Healthcare  
Lisa Santelli  Excellus  
C. William Schroth  NYS DOH  
Amelia Shapiro  Queens Health Network  
Nance Shatzkin  BX RHIO  
Tom Silvious  CSC Consulting  
Ben Smith  Physician Technology Initiatives  
Robin Smith  ARCHIE  
Steven Smith  NYS DOH  
Ben Stein  NSHS  
Seth Stein  NYS Psychiatric Association
NY HISPC Phase I Team

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Katie O’Neill, JD Legal Action Center
Jean Orzech Quarrier, JD New York State Department of Health
Sarah D. Strum, JD Catholic Health Care System
Robert N. Swidler, JD Northeast Health
Variations Workgroup

The following organizations participated in the HISPC statewide business practice variations workgroups.

ACOG
Albany Medical Center
Albany Memorial Hospital
Anheuser Busch
Association - Women's Medicine
At Home Care, Inc.
Bellevue Hospital
Bronx RHIO
Brownsville
Calvary Hospital
Cayuga Medical Center
Centrex Clinical Labs
Childrens Health Fund
Community Care Physicians
Community Health Center
Crystal Run Healthcare
Department of Corrections
Excellus Health Plan
Genesee Region Home Care & Hospice
Glens Falls Hospital
GNHYA
Greater Rochester RHIO
Greenberg Traurig LLC
Greene County Public Health
Harrison Center Outpatient
Health Care Providers
Health First
Hill Haven Nursing Home
Hometown Health Center
Hospital for Special Surgery
IBM
Institute for Urban Family Health
Interim Health Care
IPRO
Kings County Hospital
Kodak
Lab Alliance of Central New York
Lutheran Family Health
Memorial Sloan Kettering
Montefiore Medical Center
MSSNY

Solutions Workgroup

Abbondandolo, Donna
Angrignon, Rachel
Baig, Aleem
Beato, Patricia
Blair, M.D., John

North Shore LIJ Health System
Fidelis Care
Metro Plus
University of Rochester Medical Center
Taconic IPA, Inc.
Borges, Linda MVP Health Care  
Brucker, Julie Saratoga Hospital  
Burke, Donna HealthNow  
Calicchia, Eric Kate Greenberg, Traurig  
Chevalier, Lynn Next Wave, Inc.  
Cirillo, Joseph S. JD Brooklyn Hospital Center  
Clancy, Cathy Hudson Health Plan  
Cooper, Ellen New York State Assoc of Ambulatory Surgical Centers  
Ehlinger, Bryan Oneida Healthcare Center  
Ehrmentraut, Sheryl Family Champions  
Galanis, Christina So. Tier Healthlink RHIO  
Garnham, James Greater Rochester IPA  
Gillian, Paul CDPHP  
Groszewski, Walter IBM  
Heywood, Nancy NYS Dept. of Correctional Services  
Hoover, Robert Independent Health  
Iversen, Judy Visiting Nurses  
Iyer, Radhika HealthNow  
Jacomine, Douglas CDPHP  
Jaffe, Anita MVP Health Plan  
Julier, Kevin P. IBM  
Kelly, William P. Treo Solutions  
Kendall, Mat DOHMH  
Koch, Irene Maimonides Medical  
Kremer, Ted Greater Rochester RHIO  
Lurin, Joseph GHI  
MacMullen, Georgie North Shore LIJ Health System  
Majkowski, Ken Rx Hub LLC  
Martin, Donald Fidelis Care  
Martin, Dr. Glenn Queens Health Network  
Martucci, Joe NYS Cyber Security & Critical Infrastructure Coor.  
McCarthy, Kelley So. Tier Healthlink RHIO  
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Murphy, Marie Maimonides Medical  
Novak, Carla HANYS  
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Reynolds, Rita Memorial Sloan Kettering  
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Silvious, Thomas HealthNow  
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NYSDOH

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New York Association of Health Care Providers, Inc.

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Maura Bluestone  
Affinity Health Plan

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GE Healthcare

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Diane Carroll

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North Country Children's Clinic

John Cauvel  
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C. Lynn Chevalier  
Next Wave Inc

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Health Quest

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Kathleen Duffett, RN, JD, Attorney at Law

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Donna Farago  
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Debra Feinberg  
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Martin Hickey Excellus BC/BS
Jeffrey Hirsch Waiting Room Solutions
Susan Huntington Glens Falls Hospital
Matthew Jarman American Red Cross
Robin Jones CMIP
Annette Kahler Albany Law School
Mary Kenna Group Health Incorporated
Brett Kessler Bellevue Woman's Hospital
Al Kinel Kodak
Irene Koch Maimonides Medical Center
Susan Koppenhaver Eden Park Health Care Center
Ted Kremer, MPH Greater Rochester RHIO
Franklin Laufer NYSDOH - AIDS Institute
Karen LeBlanc Seton Health
Arthur Levin Center for Medical Consumers
Liz Lonergan Syracuse University College of Law
Joseph Lurin Group Health Incorporated
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Anthony Mancuso Maimonides Medical Center
Glenn Martin Queens Health Network
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Laurie Radler Montefiore Medical Center
Carol Raphael Visiting Nurse Service of New York
Rita Reynolds Memorial Hospital
Cindy Richards Northeast Health
Salvatore Russo NYC Health & Hospitals Corporation
John Shaw Next Wave Inc.
Ben Smith Greater Rochester IPA
Robin Smith ARCHIE
Joseph Sorrenti Interfaith Medical Center
<table>
<thead>
<tr>
<th>Name</th>
<th>Organization/Institution</th>
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<tbody>
<tr>
<td>Keith Stack</td>
<td>Alcoholism and Substance Abuse Providers of NYS</td>
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<tr>
<td>Susan Stuard</td>
<td>New York Presbyterian Hospital</td>
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<td>Zebulon Taintor</td>
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<td>Deborah Tokos</td>
<td>United Health Services</td>
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<td>Asha Upadhyay</td>
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<td>Teresa Yennan</td>
<td>Baptist Health</td>
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<td>Daniel Walden</td>
<td>Medco Health Solutions</td>
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<td>Mary Welch</td>
<td>Trudeau Health Systems</td>
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<td>Robert Westlake, Jr MD</td>
<td>NY Chapter, American College of Physicians</td>
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<td>John White</td>
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<td>Dianne Wilson</td>
<td>American Red Cross, New York-Penn Region</td>
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<tr>
<td>Lynn-Marie Wozniak</td>
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