

1                   **New York Health Information Security and Privacy Collaboration**

2  
3                   **Standardized Consumer Consent Policies and Procedures**  
4                   **for RHIOs in New York State**

5  
6                   **December 21, 2007**

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9  
10                  **Invitation to Comment:**

11  
12                  The Health Information Security and Privacy Collaborative (HISPC) is a national  
13                  initiative funded by the federal Office of the National Coordinator for Health IT and  
14                  Agency for Health Research and Quality to examine how privacy and security laws  
15                  impact business practices related to electronic health information exchange. The  
16                  purpose of this document from the New York HISPC team is to put forth for public  
17                  comment recommended policies and guidelines governing consumer consent for the  
18                  exchange of personal health information in a technology-enabled health care  
19                  environment facilitated by Regional Health Information Organizations (RHIOs) in New  
20                  York State in order to protect privacy and strengthen security. Comments received will  
21                  be reviewed and considered during the development of final policy guidance that will be  
22                  issued by the New York State Department of Health. Please submit written comments  
23                  utilizing the form provided on the NYS HISPC website:

24  
25                  [http://www.nyhealth.gov/technology/nyhispc/phase\\_ii/](http://www.nyhealth.gov/technology/nyhispc/phase_ii/) to the Office of Health  
26                  Information Technology Transformation by January 31, 2008 via email:

27  
28  
29                  This document is divided into the following eight sections:

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1    **I. Introduction and Background**

2  
3    Responding to growing evidence that interoperable health IT can support improvements  
4    in health care quality, affordability and outcomes, New York State is making  
5    considerable investments in transitioning its health care settings from today's largely  
6    paper-based environment to an electronic, interconnected health care system.

7  
8    On August 8, 2007, the State of New York announced an ambitious new initiative to  
9    promote interoperable health information exchange and new tools for quality and  
10   population health measurement and reporting in New York. This initiative is part of  
11   Governor Eliot Spitzer's agenda to advance patient-centered care and enable  
12   improvements in health care quality, affordability and outcomes for each person, family  
13   and business in New York.

14  
15   To launch this initiative, \$105.75 million in State funding has been committed to support  
16   the implementation of health IT infrastructure. The expected benefits include:

- 18     • **Improvements in Efficiency and Effectiveness of Care:** Provide the *right*  
19       information to the *right* clinician at the *right* time regardless of the venue where  
20       the patient receives care.
- 22     • **Improvements in Quality of Care:** Harness the power of clinical information to  
23       support improvement in care coordination and disease management, help re-  
24       orient the delivery of care around the patient and support quality-based  
25       reimbursement reform initiatives.
- 27     • **Reduction in Costs of Care:** Reduce health care costs over time by reducing  
28       the costs associated with medical errors, duplicative tests and therapies,  
29       uncoordinated and fragmented care, and preparing and transmitting data for  
30       public health and hospital reporting.
- 32     • **Improvements in Outcomes of Care:** Evaluate the effectiveness of various  
33       interventions and monitor quality outcomes.
- 35     • **Engaging New Yorkers in Their Care:** Lay the groundwork for New Yorkers to  
36       have greater access to their personal health information and communicate  
37       electronically with their physicians and designated care givers to improve quality,  
38       affordability and outcomes.

40    New York's investment in health IT is significant for many reasons, chief among them  
41    that it is by far the largest state investment to date in creating a public-private  
42    governance and operating model to support interoperable health information exchange  
43    and health IT tools for quality measurement and reporting and population health  
44    improvement. As exciting as this opportunity is, it comes at a time when the health IT  
45    environment is extremely dynamic. As New York charts its way through new waters, it  
46    must take into account and respond to many issues, including increased consumer

1 demand for health information; a newly emerging, but largely unregulated, commercial  
2 market for health information; new clinical models for personalizing care based on  
3 genetic and other types of information; new care delivery models, such as the medical  
4 home, which depend on streamlined information transfer to support the continuity of  
5 care; and new prevention and outcome-oriented reimbursement models where  
6 information is needed to measure and account for outcomes and performance. At the  
7 same time, concerns about the privacy and security of all types of personal information -  
8 especially health information - abound, with daily headlines alerting the public to the  
9 dangers of stolen laptops containing personal health information, cyber security threats,  
10 phishing and other identity theft problems.

11  
12 In pursuing its health IT investment program, New York is cognizant that its success will  
13 not only be measured by technical, operational, financial and clinical achievements, but  
14 similarly by the policy framework and rules governing the exchange, measurement and  
15 reporting of personal health information and organizations ensuring the adherence to  
16 such policies. In fact, the establishment of public trust with respect to the privacy and  
17 security of health information is the single most important goal of New York's health IT  
18 investment program.

19  
20 In pursuing this goal, New York benefits from policy thinking developed by several  
21 important initiatives which have addressed privacy and security, including: the Markle  
22 Foundation's Connecting for Health initiative; the California Healthcare Foundation's  
23 policy briefs on privacy and consumer attitudes and important policy forums; studies  
24 advanced by such organizations as the American Health Information Management  
25 Association (AHIMA), eHealth Initiative, Healthcare Information Management Systems  
26 Society (HIMSS), and National Alliance for Health Information Technology (NAHIT), the  
27 Health Information Security and Privacy Collaborative (HISPC); and the Certification  
28 Commission on Healthcare Information Technology's (CCHIT) work on privacy and  
29 security-related product certifications. In a very real sense, New York's investment  
30 program builds on the collective foundation of these policy efforts and at the same time  
31 seeks to go one step further. Because New York is setting policy in the context of live  
32 implementations and is doing so through a statewide public-private collaborative model  
33 it presents a unique opportunity to stress test new concepts which to date have largely  
34 been considered in either much smaller settings, on a theoretical basis or based on  
35 proprietary and/or narrow technological approaches. Hopefully, New York's experience  
36 will provide all stakeholders a much richer understanding of what works and what  
37 doesn't work, and will help to inform and shape emerging state and national policy.  
38

## 39 **Achieving Interoperability**

40 A central strategic focus of New York State's efforts is to advance interoperability  
41 through the development and implementation of a shared health information  
42 infrastructure based on a community-driven model available to all providers, payers and  
43 patients. The State health IT framework supports common policies, technical standards  
44 and protocols, as well as regional "bottom-up" implementation approaches and care  
45 coordination to allow local communities and regions to structure their own efforts based  
46 on clinical and patient priorities. The framework seeks to promote innovation across the

1 diversity of New York's health care delivery settings - from solo physician offices and  
2 community health centers to large academic medical centers, nursing homes and multi-  
3 specialty physician practices, from Manhattan to rural upstate towns - with vastly  
4 differing market conditions and health care needs.

5  
6 Interoperability is essential to realizing the expected benefit from health IT; vastly  
7 improving the availability and use of health information to improve patient care.  
8 Perpetuating siloed information systems that do not interconnect will significantly  
9 impede the adoption and effective use of health IT tools. Interoperability enables  
10 patient health information to be exchanged in real time among disparate clinicians, other  
11 authorized entities and patients while ensuring security, privacy and other protections.  
12 Interoperability is necessary for compiling the complete experience of a patient's care  
13 and ensuring it is accessible to clinicians as the patient moves through various  
14 healthcare settings. This will support clinicians in making fact-based decisions so  
15 medical errors and redundant tests can be reduced and care coordination improved.  
16 Interoperability is critical to cost-effective, timely and standardized data aggregation and  
17 reporting for quality measurement, population health improvement, biosurveillance, and  
18 clinical research. Interoperability is also needed for patients to have access to their own  
19 personal health information, enabling it to be portable, not tethered to a particular payer  
20 or provider.

21  
22 To ensure interoperability, the State is seeking to support the implementation of three  
23 interrelated components of New York's health information infrastructure –  
24 organizational, clinical and technical. The successful implementation of New York's  
25 health information infrastructure must emerge from these three intertwined capabilities  
26 in order to realize the benefit of health information with respect to improving health care  
27 quality, reducing costs and improving outcomes for all New Yorkers. Achieving these  
28 benefits is dependent on much more than just technology. For example, interoperability  
29 is as much a function of trust as technology or clinical participation, and is achieved  
30 through policy and governance.

31  
32 The high-level technical framework for New York's health information infrastructure is  
33 comprised of three main layers and is depicted in figure 1 below<sup>1</sup>.

- 34
- 35     • **A Statewide Health Information Network for New York (SHIN-NY)** is a  
36         network of networks to interconnect clinicians to exchange patient information  
37         regardless of the venue in which the patient receives care in order to deliver the  
38         right care at the right time in a coordinated, patient-centered manner. The SHIN-  
39         NY will utilize the Internet and include common software protocols and services,  
40         including security tools, and will be a part of the emerging Nationwide Health  
41         Information Network (NHIN).

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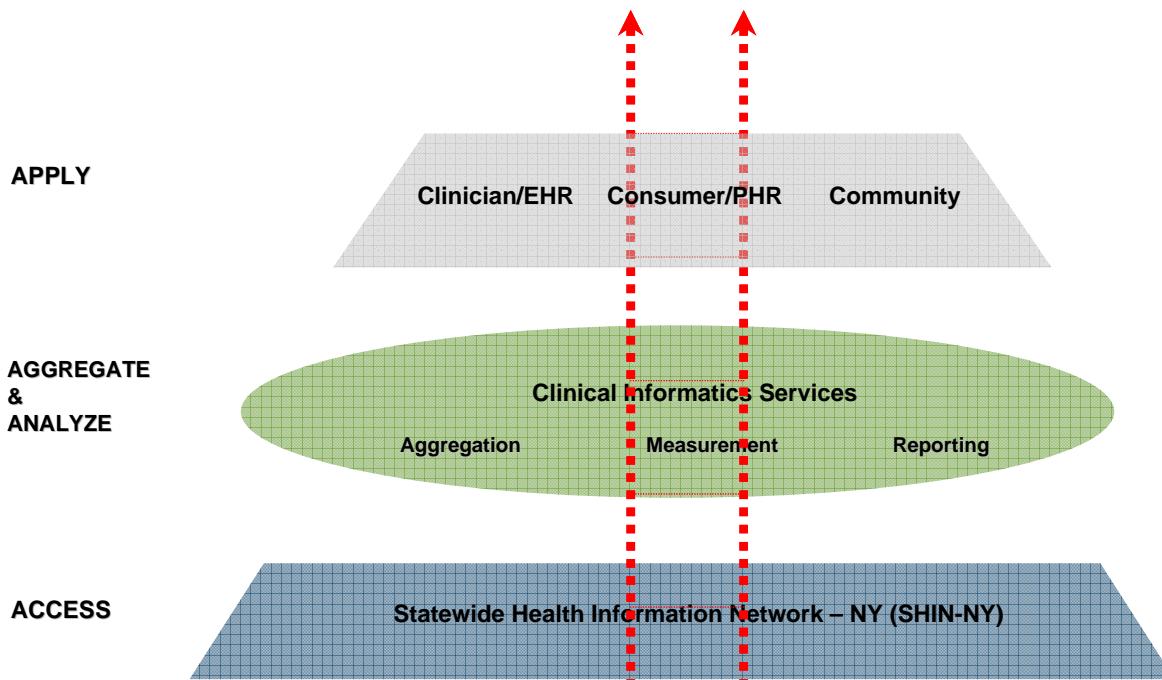
<sup>1</sup> For additional information, a technical discussion document published as part of the HEAL NY Phase 5 Health IT RGA is located on the DOH website: <http://www.nyhealth.gov/funding/rfa/0708160258/>

- **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

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

18  
19 As described more fully below in Figure 2 below, there are seven critical components of  
20 the definition of a RHIO.

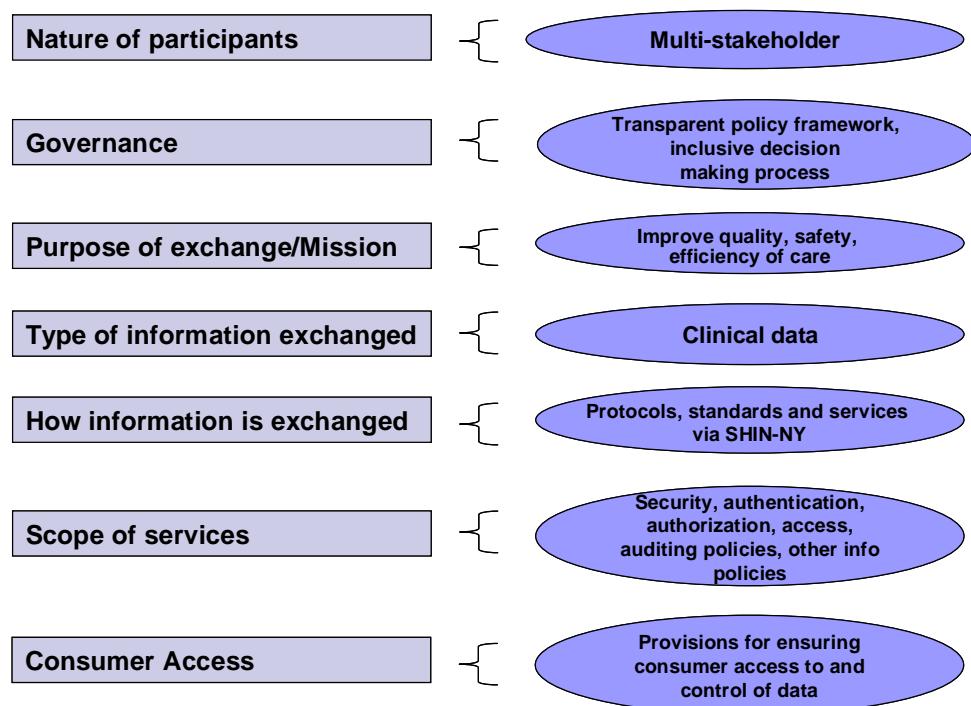
21

22 **Figure 2**

23

24 **Seven Critical Components of the RHIO Definition**

25



26

1  
2 One of the main functions of a RHIO is to act as a governor or trusted broker to  
3 establish, maintain and enforce privacy and security policies for multiple entities and for  
4 multiple purposes. Establishing a trusted broker for health information is not merely a  
5 matter of implementing a technical solution compliant with State and federal law. It  
6 requires developing consensus and trust around value-laden policy decisions, which are  
7 then translated into business procedures and eventually reflected in contractual  
8 relationships between RHIO participants.

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

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

21  
22 It also is important to recognize that the recommendations in this paper provide a  
23 starting point for a longer discussion. While the recommended policies outlined below  
24 are often specific and directive in nature, more detailed guidance will be necessary to  
25 enable full implementation.

26

## 27 **Consumer Access Services - Supporting the Right of New Yorkers to Have 28 Greater Control Over and Access to Their Personal Health Information**

29

30 As we advance health IT in New York, there is a significant opportunity to expand the  
31 way in which we have traditionally thought about consumer rights to access and use  
32 their own personal health information. Consumer access to and use of their personal  
33 health information is necessary to realize the full potential of the range of  
34 technologically-enabled care advancements. Redefining consumers' rights, however,  
35 will require a paradigm shift in how we think about health information – supplementing  
36 the current legal structure which focuses on clinician control over the medical record  
37 and under what circumstances disclosures of such information are permissible - with a  
38 new legal structure that affirmatively provides consumers with the right to gain access to  
39 their personal health information, regardless of the source of such information, and  
40 supports the consumer's ability to maintain such information for his or her personal use.  
41 While consumer access services and personal health records are not the focus of this  
42 paper, it is important to note that RHIOs can, and hopefully will, play an important role in  
43 enhancing consumer access to their own personal health information.

1      **II. The Health Information Privacy and Security Collaboration (HISPC): Project**  
2      **Goals and Work Plan**

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

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

14

15      **NY HISPC Phase I**

16      In 2006, New York State was one of 34 States and territories awarded a HISPC  
17      contract. The New York State Department of Health (NYS DOH) served as the lead  
18      agency for this project in New York State. Phase I spanned from March 2006 to April  
19      2007 and involved a comprehensive assessment of health privacy legal and policy  
20      issues in New York State. Major findings of NY HISPC Phase I included the following:

- 21
- 22            • **Human Judgment in Information Exchange:** Information exchange currently  
23          relies heavily on human judgment and interaction to ensure security and privacy  
24          of health information
- 25            • **From One-to-One to Many-to-Many:** Moving to a broad transfer of information  
26          to many persons or entities may require layers of sophisticated permissions and  
27          controls.
- 28            • **Informed Patient Consent:** Informed patient consent that is meaningful,  
29          tracked and monitored is a key requirement to earning patient trust in HIE.
- 30            • **Sensitive Data:** Differing regulations governing specially protected health  
31          information present challenges for staff education and compliance.
- 32            • **Appropriate Scope of Disclosure:** There is a need to more clearly define who  
33          needs to see what information and to understand how to accommodate  
34          appropriate access in an electronic environment.
- 35            • **Patient Care and Patient Privacy:** There exists a delicate balance between  
36          patient privacy and the need for information for treatment.
- 37            • **Security in an Electronic World:** There is a heightened sense of vulnerability  
38          regarding identifiable health care information in electronic form.
- 39            • **Patient Control:** There is an opportunity to create an environment that supports  
40          the right of consumers to control the use of their own personal health information.

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

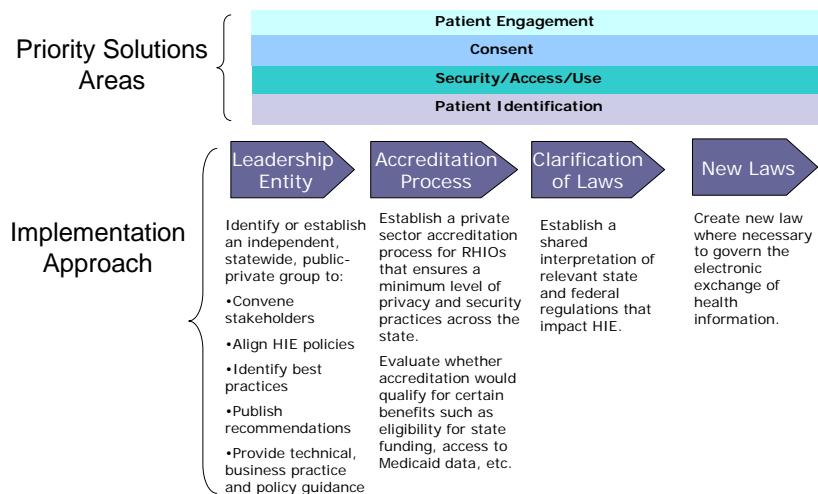
4  
5     A central finding of phase one of HISPC was that strong policies that protect the privacy  
6       and security of health information are crucial to achieving interoperable health  
7       information exchange. Current laws governing HIE and the resulting business practices  
8       were developed in the context of a paper-based health care setting where decisions on  
9       what to communicate, how and to whom are generally made on a one-to-one basis by  
10      clinicians. The current laws attempt to serve the patient's privacy interests by restricting  
11      what can and cannot be shared and the terms on which sharing takes place. Human  
12      judgment and personal relationships play a major role, as clinicians attempt to act as  
13      the guardian of their patients' information. Moving from a paper to an electronic health  
14      system changes the information sharing dynamic. An interoperable health system  
15      facilitates a many-to-many relationship, enabling different information technology  
16      systems and software applications to exchange information accurately, effectively, and  
17      consistently. This offers new opportunities for patient access to and control over their  
18      health care information, as well facilitating the safety, quality and efficiency of their care.  
19      However, it also demands new approaches for protecting patient privacy and security,  
20      including policies addressing the disclosure and use of health care information, and  
21      technologies that address patient identification, authentication, record location, identity  
22      management, and storage of special classes of information.

23  
24     The NY HISPC Phase I advanced an "Implementation Framework" highlighted in Figure  
25      3 below. One of the four priority solution areas was consumer consent – ensuring that  
26      consumers are able to provide informed and meaningful consent and that holders of  
27      consumer health information adhere to State and Federal privacy and security laws as  
28      they exchange health information electronically.

1      **Figure 3**

2

3      **NY HISPC Phase I Implementation Framework**



4

5

6      **NY HISPC Phase II**

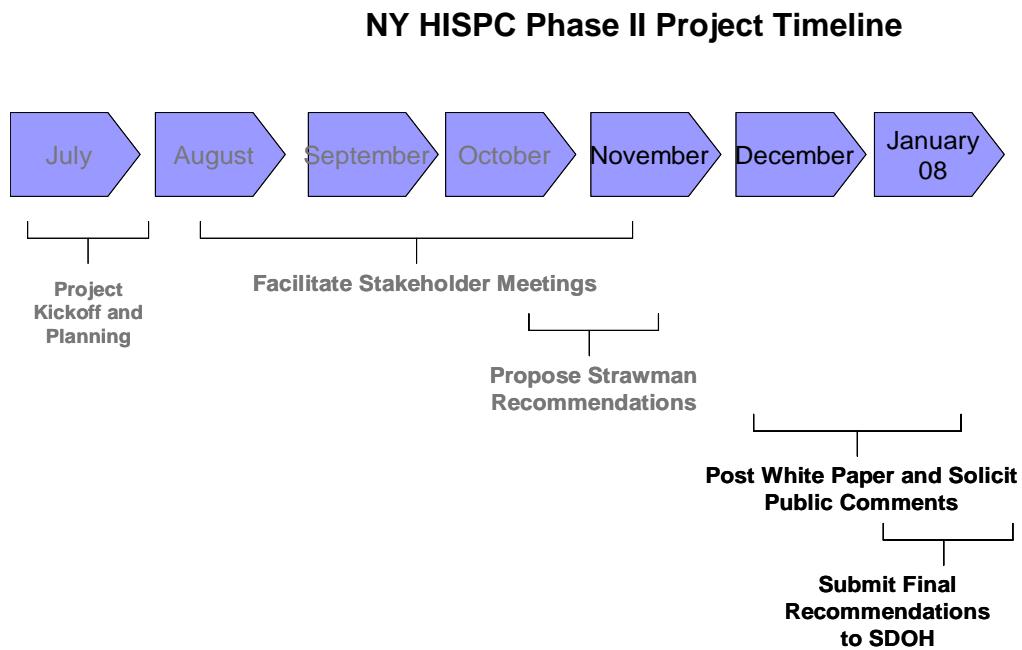
7      The second phase of NY HISPC began in June 2007, with NYS DOH as the lead  
8      agency, and has focused on implementing a patient consent solution through the  
9      development of a standardized consent process. The goal of this standardized process  
10     is to promote consistency across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

- 14     • Advance health information exchange via the SHIN-NY through the development  
15     of a standardized consent process implemented through and facilitated by RHIOs  
16     in NYS
- 17     • Ensure that consumer consent is informed and knowing
- 18     • Provide clarity on and ensure consistency in consent process
- 19     • Give RHIOs standing to address patient consent on behalf of physicians,  
20     providers and New Yorkers
- 21     • Enable incentives and protections to encourage RHIO participation.

22

23     The duration of the project is from June 2007 through January 2008; the process is  
24     represented in Figure 4, below:

1    **Figure 4**



1      **Figure 5**

2  
3      **Key Questions for Developing RHIO Consent Standards**

4  
5  
6      Activities: What are the activities with respect to health information  
7      exchange we are seeking to govern and support?

8  
9      Obligations: What are the core obligations of a RHIO governing health  
10     information exchange via SHIN-NY with respect to consumer consent?

- 11     • Uses of information  
12     • Sensitive information  
13     • Where and at what point consent is obtained  
14     • Standardized consent process  
15     • Durability and revocability  
16     • Consumer engagement  
17     • Audit and transparency

18      Benefits/Penalties: What are the consequences, including benefits and  
19      penalties, of meeting the obligations defined above?

20      Adoption/Compliance: How and by whom will compliance be enforced?

21  
22  
23     At the third meeting, “straw model” recommendations were proposed and discussed.  
24     The policy guidance described in this document is the result of the discussion during  
25     those three meetings.

26  
27     This document outlines a standardized consent process, related roles and  
28     responsibilities of RHIOs and participants as trusted custodians of health care  
29     information, and consumer protection safeguards required to prevent inappropriate use  
30     or disclosure of consumer health information. The policies described are still under  
31     development. As such, public comments are strongly encouraged.

32  
33      **II. The Need for a Standardized Consent Process for RHIOs in New York State**

34  
35     RHIOs across the State are struggling to define what constitutes adequate and  
36     meaningful patient consent. Broad variation in opinion exists among stakeholders as to  
37     what is required legally, what is appropriate for risk management purposes, what  
38     constitutes the best public policy, what is best for New Yorkers and what is feasible from  
39     an implementation perspective. Standardized consent policies will help earn patient  
40     trust, provide clarity regarding compliance with New York law and ensure  
41     interoperability via the SHIN-NY enabled and governed by RHIOs.

42  
43      **Standard Consent Policies for RHIOs are Necessary to Ensure Complete and  
44     Consistent Health Information and Earn Patient Trust**

1 Electronic health information exchange represents a paradigm shift in the way  
2 information is exchanged between a consumer's health care providers. In today's  
3 largely paper-based world, exchange of health information between providers generally  
4 is managed by the consumer. In order for Provider A to obtain health information from  
5 Provider B, the consumer must tell Provider A that they are receiving care by Provider B  
6 and would like their health information to be shared. The consumer in effect is the  
7 gatekeeper of a one-to-one relationship among various providers who are responsible  
8 for their care.

9

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

21

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

34

35 **RHO Consent Standards will Facilitate Interoperability via SHIN-NY**

36 New York State offers a fragmented State legal and regulatory framework on consumer  
37 consent. Unlike HIPAA, New York's extensive legal requirements governing the  
38 collection, storage and exchange of health information are not organized into a single  
39 regulatory scheme. State law governing health information is spread across dozens of  
40 statutory and regulatory provisions. The result is a patchwork of requirements and  
41 exceptions that vary greatly depending on the nature of the entity, type of information  
42 involved and purpose of the disclosure. Gaps in legal/regulatory guidance result in  
43 varying interpretations and diverse consumer consent policies across RHOs. This is  
44 apparent in the current HEAL NY Phase 1 funded projects, which have come to differing  
45 conclusions about the mandates under state law, and are implementing a wide range of  
46 patient consent policies as a result. Diverse consent policies are a barrier to

1 interoperability. A standardized consent process will enable consistency across RHIOs,  
2 eliminate interoperability barriers and reassure consumers that all RHIOs adhere to  
3 minimum privacy standards with regard to exchange of their health information.

4

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

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

19

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

22 It is crucial that the state ensure adequate policies and standards are in place to protect  
23 the integrity of RHIO activities and the privacy of the public. HIPAA applies only to  
24 "covered entities," which include certain health care providers, health plans and health  
25 care clearinghouses. RHIOs are not health care providers, health plans or  
26 clearinghouses<sup>2</sup>. Accordingly, at the present time, it does not appear that any of the  
27 RHIOs will be covered entities.

28 Under HIPAA, a business associate is an organization that assists a covered entity in  
29 performing certain health-related or administrative functions, and receives, creates or  
30 maintains protected health information in connection with these activities. To date, most  
31 if not all RHIOs in New York have been structured as business associates of RHIO  
32 participants under two basic models:

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

---

<sup>2</sup> 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.

- 1     • “**Custodial CDR” Model:** The RHIO supports a CDR in which each provider’s  
2       data is stored. Each provider continues to own its data. The RHIO holds the  
3       data on behalf of each provider as a custodian, and has no ownership rights in  
4       the data. If a provider leaves the RHIO, the provider’s data must be returned or  
5       destroyed. Under this model, the RHIO *is* a business associate of each provider.

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

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

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

30

### 31 III. Key Principles and Stakeholder Priorities

32  
33    The recommended policies for obtaining consumer consent to exchange personal  
34      health information via the SHIN-NY governed by RHIOs were guided by several key  
35      principles, summarized in Figure 6.

36

37

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42

1      **Figure 6**

2

3      **Key Principles of New Consent Policies and Procedures**

4

- 5
- 6      ➤ Promote patient-centered care by facilitating consumer choice  
7      and addressing consumer concerns about privacy
- 8      ➤ Promote exchange of comprehensive information ensuring  
9      clinical effectiveness to improve the quality and efficiency of  
10     care
- 11     ➤ Minimize burdens on healthcare providers
- 12     ➤ Be practical and “implementable” for RHIO participants  
13     providing operational flexibility
- 14     ➤ Be simple and clear with a concrete rationale
- 15     ➤ Foster innovation while ensuring public trust
- 16     ➤ Be neutral on technology model

17     These principles outline the core policy aspirations and practical considerations  
18     necessary to implement interoperable health information exchange. Buy-in from  
19     multiple stakeholder groups is important, and throughout the course of the public  
20     meetings it was clear that stakeholders approach RHIOs with a host of pressing needs.

- 21     • **Consumers:** Consumers seek assurance that they have a meaningful level  
22     of control over who is able to access their protected health information. They  
23     want choices and they want to have enough information in the consent  
24     process to make that choice meaningful and knowing. Consumers want to  
25     know that those who have access to their information use it to improve the  
26     delivery and quality of their care, and do not use it in a way that could cause  
27     them embarrassment or harm. Consumers are particularly concerned that  
28     their sensitive health information is protected and only viewed by authorized  
29     individuals for whom they enable access.
- 30     • **Clinicians:** Clinicians want to ensure clinical effectiveness and high quality  
31     care. They want access to a consumer’s complete medical record at the  
32     point of care to enable the provision of consistent, high quality and safe  
33     medical care. They are equally concerned that consent requirements do not  
34     impose heavy burdens on them and their staff, especially for doctors in small  
35     practice settings.
- 36     • **Provider Organizations:** Provider organizations want assurance that  
37     additional consent requirements do not impose heavy administrative,  
38     technical and/or financial burdens on their organization and its resources.  
39     Such institutions often already have internal information systems and want to  
40     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:

1      **Figure 7**

2

3      **Recommended Policies and Standards for Consumer Consent to Exchange**  
4      **Information via SHIN-NY governed by RHIOs**

- 5      1) **Scope of Governed Activities:**  
6      The new consent rules apply statewide to interoperable health information  
7      exchange of patient identifiable health information via SHIN-NY governed by  
8      RHIOs and their participants.
- 9      2) **Affirmative Consent:**  
10     Each provider organization and payer organization participating in a RHIO must  
11     obtain an affirmative consent from the consumer that specifically references the  
12     RHIO prior to accessing her/his personal health information.
- 13     3) **Up-Loading Data:**  
14     Health care providers may “upload” patient information to a RHIO without  
15     patient consent.
- 16     4) **Uses of Health Information:**  
17     Permissible uses of health information fall into two categories, each requiring  
18     different types of consent.
- 19     5) **Sensitive Health Information:**  
20     A single consent may be obtained to exchange all health information, including  
21     all specially protected health information.
- 22     6) **Consent Form:**  
23     RHIOs must use a State-approved consent form.
- 24     7) **Durability and Revocability:**  
25     RHIO consents are both durable and revocable.
- 26     8) **Consumer Engagement and Access:**  
27     RHIOs must comply with consumer education, engagement and access  
28     standards.
- 29     9) **Audits and Transparency:**  
30     RHIOs must conduct audits at least annually; inform consumers promptly of any  
31     breaches and make audit trails available upon request. It is anticipated that on-  
32     line tools and paper-based reports will be utilized.
- 33     10) **Benefits and Penalties:**  
34     To be eligible for State funding through HEAL and other initiatives, and to  
35     receive Medicaid data, RHIOs must adhere to consent policies.
- 36     11) **Enforcement:**  
37     Consent standards initially will be enforced through contractual relationships  
38     between RHIOs and New York State, and should migrate towards requirements  
39     for an accreditation process.

1           **Scope of Governed Activities:** The new consent rules apply  
2           statewide to health information exchange of personal health  
3           information via the SHIN-NY governed by RHIOs and their  
4           participants.

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

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

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

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

31      One exception relates to “one-to-one” electronic health information exchange. “One-to-  
32      one” health information exchange taking place through a RHIO is not subject to new  
33      consent policies. One-to-one exchange is best described as a request by a treating  
34      clinician to receive information from or send information to an identified source (i.e.  
35      either another clinician or an ancillary service provider.) Common examples include  
36      physician referrals, a discharge summary being sent by a treating hospital to the  
37      referring physician, or the delivery of lab results to the clinician who ordered the test.  
38      One-to-one exchanges utilize technology to transfer information in a way that mirrors  
39      paper-based exchange, in essence, simply replacing the facsimile machine with email.  
40      Each one-to-one exchange is understood and predictable to the patient, and limited in  
41      scope to the two exchanging providers.

1 RHOs may include one-to-one exchange services among their offerings. So long as  
2 the RHIO has the capacity to separate this exchange – including policies and tools that  
3 enable the types of exchanges within the RHIO to be readily distinguishable – RHOs  
4 need not apply the new consent policies to one-to-one components of the exchange.  
5 Obviously, consent requirements in existing law applicable to any one-to-one exchange  
6 remain in force.

7  
8 The “one-to-one” exception is important to avoid significant unintended consequences  
9 that could impact a range of electronic health information exchange activities that are  
10 adequately regulated and do not constitute community-wide or statewide health  
11 information exchange. However, further guidance is required to clearly distinguish the  
12 line between “one-to-one” and community-wide/statewide exchange. More deliberation  
13 and guidance is necessary regarding the boundaries of “one-to-one” exchange to  
14 ensure that it is enforceable and effective, and does not disrupt existing techniques for a  
15 clinician and provider to access information he/she ordered for a patient.

16  
17 It also is important to note that to the extent public health reporting does not require  
18 consumer consent under New York law, consent requirements related to RHOs do not  
19 apply to information exchange related to such reporting. However, public health  
20 reporting has been recognized as a high priority for RHIOs in New York and RHIOs are  
21 encouraged to integrate public health reporting into consumer education efforts.

22  
23 Furthermore, the new consent policies and procedures for RHIOs apply only to  
24 identifiable data. According to HIPAA, “de-identified health information neither identifies  
25 nor provides a reasonable basis to identify an individual.” While greater clarity is  
26 required regarding consent policies and procedures for de-identified data exchanged  
27 through a RHIO for quality and population health measurement and reporting, clinical  
28 research, among other purposes, this requires further deliberation that is beyond the  
29 scope of this initiative and should be further developed through the statewide  
30 collaboration process and approved by the State.

31  
32 Finally, minimum technical protocols, standards and services serve as the floor for  
33 RHIO policies and practices. RHIOs may choose to implement policies and practices  
34 that exceed the protocols, standards and services defined by the state.

35  
36       **Affirmative Consent:** Each provider organization and payer  
37       organization participating in a RHIO must obtain an affirmative  
38       consent from the consumer that specifically references the RHIO  
39       prior to accessing her/his personal health information.

40 Affirmative consent must be obtained by each provider and payer organization before  
41 accessing health information via the SHIN-NY governed through the RHIO. Consent to  
42 providers may be done at a provider or organizational level (e.g. medical practice,  
43 hospital) and need not be at the individual clinician level. Once a provider obtains  
44 patient consent, it may access the information of all other participating providers unless  
45 the RHIO has voluntarily established additional restrictions on disclosures as indicated  
46 below. It is required that providers and payers each obtain consent prior to accessing

1 information; a one time general consent which provides multiple organizations with  
2 simultaneous consent will not be permissible for reasons discussed in Section VII.  
3  
4 Providers and payers may, at their discretion, also seek consent prior to *disclosure* of  
5 personal health information, but are not required to do so. This option is likely to be of  
6 special interest to providers of particularly sensitive health services (e.g. family planning  
7 and abortion service providers) because it would limit the access of other health care  
8 providers (who had obtained their own consents) to this sensitive information unless the  
9 patient expressly authorized the provider of the sensitive services to make the  
10 information available.

11  
12 Consumers must be able to prevent any or all provider and payer organizations from  
13 accessing their personal health information via SHIN-NY governed by a RHIO without  
14 being refused treatment or coverage.

15  
16 In an emergency situation in which the consumer is unconscious or otherwise unable to  
17 give or withhold consent, and the treating clinician determines that information that may  
18 be held by the RHIO may be material to treatment, and the consumer has not previously  
19 withheld consent for the provider organization to access his/her information, the RHIO  
20 may allow the physician to access the consumer's information through "break the glass"  
21 capability. The physician must attest that all of these conditions apply, and the RHIO  
22 software must maintain a record of this access.

23  
24 As indicated above, the transfer of data to an "Owner CDR" model would require a  
25 HIPAA authorization in addition to meeting state standards related to affirmative  
26 consent.

27  
28       **Up-Loading Data:** Health care providers may upload patient  
29       information to the SHIN-NY governed by a RHIO without patient  
30       consent.

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

39  
40 To date, New York regulatory authorities have not interpreted the State's existing  
41 medical privacy laws as requiring patient consent for the storage or management of  
42 data by technology vendors acting on behalf of health care providers. If a vendor holds  
43 patient data solely as a custodian of the provider and does not make the data available  
44 to other entities, the storage arrangement is not treated as a "disclosure" to a third party  
45 requiring consent under New York law. Accordingly, existing New York law does not  
46 require providers to obtain patient consent to upload information to a RHIO as long as

1 the RHIO does not make the information accessible to other entities without patient  
2 consent. No change in New York law is required in this area.

3  
4 This approach regarding patient consent is appropriate for three primary reasons. First,  
5 information uploaded to a RHIO will not be viewed by other entities, and therefore  
6 patient privacy will not be compromised. Second, the information held by the RHIO will  
7 be subject to the RHIO's obligations under its business associate agreements, which  
8 track HIPAA requirements. Third, uploading information in this manner will expedite  
9 providers' access once patient consent is obtained or in an emergency thereby making  
10 important clinical information available at the point of care. .

11  
12 It is worth noting that the concept of "up loading" data – where information is held on  
13 behalf of a provider or payer by a business associate – is not possible where the RHIO  
14 is acting as an Owner CDR. RHIOs operating under an Owner-CDR model would be  
15 required to obtain a HIPAA authorization and affirmative consent before any transfer of  
16 data would be permissible.

17  
18       **Uses of Health Information:** Permissible uses of health information  
19 fall into two categories, each requiring different standards of consent.

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

- 26  
27       • **Treatment:** Treatment is defined as the provision, coordination, or management  
28 of health care and related services among health care providers or by a health  
29 care provider, and may include providers sharing information with a third party.  
30 Consultation between health care providers regarding a patient; and the referral  
31 of a patient from one health care provider to another also are included within the  
32 definition of treatment.

- 33  
34       • **Quality Improvement and Disease Management:** These activities include  
35 conducting quality measurement, assessment and improvement activities,  
36 including outcomes evaluation and development of clinical guidelines,  
37 population-based activities relating to improving health or reducing health care  
38 costs, clinical decisions support and evidence-based clinical protocol  
39 development, case management and care coordination, contacting of healthcare  
40 providers and patients with information about treatment alternatives, and related  
41 functions.

42  
43 Any entity accessing information must have had a relationship with the individual who is  
44 the subject of the information and the information must pertain to such relationship. In

1 addition, disclosure of information for quality improvement purposes must be restricted  
2 to the “minimum necessary,” consistent with requirements under HIPAA.

3  
4 Level 2 Uses are less likely to be anticipated by the consumer or to bring direct personal  
5 benefit. Level 2 Uses include research, marketing and other uses that are not Level 1  
6 or prohibited. Descriptions of Level 2 Uses include:

- 7
- 8     • **Research:** Research means a systematic investigation, including research  
9       development, testing, and evaluation designed to develop or contribute to  
10      generalizable knowledge, including clinical trials.
  - 11     • **Marketing:** Marketing means any communication about a product or service that  
12       encourages recipients to purchase or use the product or service; or an  
13       arrangement whereby a RHIO participant discloses consumer health information  
14       to another entity, in exchange for direct or indirect remuneration, for the other  
15       entity to communicate about its own products or services encouraging the use or  
16       purchase of those products or services.

17 Standards for obtaining consent for Level 1 and Level 2 Uses will differ, with a more  
18 streamlined process for Level 1 Uses and higher restrictions for Level 2 Uses.

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

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

24  
25     **Sensitive Health Information:** A single consent may be obtained to  
26       exchange all health information, including specially protected health  
27       information.

28  
29 A single consent may be obtained to exchange all health information, including HIV,  
30 mental health and genetic information, which must specifically be referenced in the  
31 consent form. An exception to this rule is information from designated substance abuse  
32 providers that are subject to current Federal law. Further guidance related to consent to  
33 exchange information from federally qualified substance abuse providers through a  
34 RHIO currently is being sought through the national HISPC process. Pending that  
35 guidance, standards on the exchange of substance abuse information is expected to  
36 mirror other specially protected health information.<sup>3</sup>

37  
38 RHIOs and their participants may, but are not required to, offer consumers the ability to  
39 screen certain types of sensitive information from exchange through the RHIO.

---

<sup>3</sup> 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.

1 Clinicians must have the discretion, in consultation with their patients, to withhold  
2 information from the health information exchange.  
3  
4 To ensure that consumers have knowledge of which providers are making the  
5 consumer's health information available through the RHIO, consumers must be  
6 informed of the RHIO participants at the time of consent. If the RHIO enters into  
7 contractual arrangements to share data with other RHIOs, consumers must be informed  
8 of which RHIOs they share such information. Consumers also must be informed that  
9 RHIO participants change over time and be given instructions on how to learn about  
10 changes in RHIO participants. RHIOs must make available to consumers real time  
11 information on which entities are participating in the exchange.

12  
13 **Consent Form:** RHIOs must use a State-approved consent form.

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

18 The standardized consent form required for Level 1 Uses must include the following:  
19

- 20
- 21 • A description of the intended uses;
  - 22 • What information is being exchanged including specific reference to HIV, mental  
23 health and genetic information;
  - 24 • The consumer's right to revoke consent; and
  - 25 • Information about who is participating in the exchange including through data  
26 sharing relationships with other RHIOs and how to stay informed about  
27 participants in real time.

28 The standardized consent form required for Level 2 Uses must include all of the above  
29 plus information about:  
30

- 31
- 32 • The specific entities with whom information will be disclosed;
  - 33 • For what specific purpose information is being exchanged;
  - 34 • Whether information is subject to re-disclosure;
  - 35 • Whether the RHIO or its participants will benefit financially from exchange of the  
36 data; and
  - 37 • The expiration date of the consent.

38  
39 Certain Level 2 Uses may require an authorization under HIPAA. As discussed above,  
40 all exchange under the Owner CDR model also would require a HIPAA authorization. It  
41 may be possible to combine the HIPAA authorization and the standardized state  
42 consent form into a single document.  
43

1                   **Durability and Revocability:** RHIO consents are both durable and  
2                   revocable.

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

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

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

20  
21                  Robust consumer education standards will be developed and approved by the State to  
22                  ensure that consumers are aware of what they are consenting to and to whom their  
23                  personal health information is available. RHIOs must conform to consumer education  
24                  program standards developed by a statewide collaboration process and approved by  
25                  the Department of Health.

26  
27                  RHIOs must appoint at least one consumer representative to its Board. A consumer  
28                  representative is defined as a person whose interest in the RHIO is as a patient or  
29                  representative of patients and who does not otherwise participate in or have a financial  
30                  interest in the operation of a RHIO.

31  
32                  RHIOs must have policies in place related to consumers' access to their own health  
33                  information through the RHIO and must inform consumers of those policies through  
34                  their education efforts. Both the federal privacy regulation and state law mandate that  
35                  certain covered entities and health care providers provide people with access to their  
36                  own health data. However, the law does not require the information be disclosed in  
37                  electronic form, even if such capacity exists. People often experience cost and  
38                  bureaucratic hurdles in getting copies of their health information, particularly if an acute  
39                  or chronic illness is involved, or if there are multiple providers. Thus, RHIOs pose an  
40                  opportunity for consumers to have one-stop-shopping, requesting their dispersed  
41                  information through a single electronic portal. At this early stage of development,  
42                  RHIOs should set their own policies as to the form, time period and cost for responding  
43                  to such requests. However, in the future, guidelines as to consumer access should be  
44                  developed as part of the statewide collaboration process.

45

1 It is worth noting that as the market for consumer-driven health information products  
2 grows, RHIOs will have increasing opportunities to work with third parties to facilitate  
3 consumer access to their personal health information. A number of companies are  
4 planning to offer software applications and services that will give consumers the ability  
5 to organize and keep their personal health information in electronic form as a Personal  
6 Health Record. Under current law, it is permissible for RHIOs to provide information to  
7 such companies, provided such information is obtained through a valid state law  
8 consent and, where necessary, HIPAA authorization. However, there is currently no  
9 state regulatory framework for regulating third parties who gain access to information  
10 through a HIPAA authorization and state law consent representing a gap in current law.  
11 Use of such information therefore would be governed by (i) the terms of the consent; (ii)  
12 the RHIO's contract with the third party and (iii) the privacy policies of the third parties.  
13 While beyond the scope of this paper, it is crucial that further consideration be given  
14 and policy guidance developed to help RHIOs ensure protection of consumer interests  
15 while facilitating consumer access to and control of their personal health information  
16 through such third party arrangements. In the interim, the policies in this paper can be  
17 looked to for guidance. Until such policy guidance is developed, proposals involving  
18 state funds will be reviewed on a case-by-case basis to ensure adequate protection of  
19 consumer interest.

20

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

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

32

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

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

42

43       **Enforcement:** Consent standards initially will be enforced through  
44 contractual relationships between RHIOs and New York State, and  
45 should migrate towards accreditation.

1 It is well understood that RHIOs are in the early stages of building their organizational  
2 infrastructures and that much will be learned in the next several years with respect to  
3 different models for ensuring consumer participation in health information exchange. In  
4 the short term, RHIOs will be expected to implement the consent provisions adopted by  
5 the State as part of their contractual agreements with the State. Such provisions will be  
6 considered in light of the specific needs of each project allowing adequate time to  
7 implement the consent procedures and, if necessary, transition from other models  
8 deployed. Contractual agreements with the State will also take into account that  
9 consent policies and procedures can be expected to evolve over the next few years  
10 through a statewide collaboration process.

11  
12 In the longer term, it can be expected that RHIOs will be subject to a broader State  
13 regulatory framework which may include accreditation of RHIO governance, privacy and  
14 security policies and other policies viewed as critical to the RHIO's role in establishing  
15 public trust as to the collection, storage and use of personal health information,  
16 protection from liability under certain circumstances and defined penalties for breach of  
17 RHIO obligations.

18  
19 For public trust to develop there must be an open and transparent process for  
20 establishing and monitoring RHIOs or similar entities charged with ensuring the privacy  
21 and security of health information. Accreditation is the best vehicle for ensuring  
22 accountability. An independent accreditation entity would include public and private  
23 representation, ensuring input from consumers and other industry stakeholders. Ideally,  
24 the accrediting entity would function as a public-private partnership, so that compliance  
25 with accreditation criteria would confer benefits and penalties by State and Federal  
26 officials. Additionally accreditation criteria would evolve as the health information  
27 exchange movement matures allowing state and federal governments to recognize the  
28 process accordingly instead of dictating one that is subject to continuous evolution for  
29 the next several years. An accreditation process for RHIOs as entities governing health  
30 information exchange would also mitigate state-by-state health information exchange  
31 regulation perpetuating and exacerbating the current patch work of state laws severely  
32 limiting multi-state and nationwide health information exchange.

33  
34

## 35 V. Discussion of Policy Considerations

36  
37 **Enables consumers to make informed decisions regarding their personal health**  
38 **information and promotes trust.**

39 While national surveys reveal that consumers generally support electronic collection,  
40 storage and exchange of health information, concerns about the privacy and security of  
41 their health information remain pervasive.<sup>4</sup> An affirmative consent prior to accessing  
42 personal health information is critical to earn consumer trust in RHIOs and to preserve

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<sup>4</sup> California Health Care Foundation. National Consumer Health Privacy Survey. 2005; Markle Foundation. Americans Want Benefits of Personal Health Records. June 2003.

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

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

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

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

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

39 **Supports payer access for the purposes of care management**

40 The recommendations seek to facilitate broad use of health information for uses that  
41 promote good medical care and treatment, whether such uses are part of provider or  
42 payer directed initiatives. Consumer always have the right to limit access of any

1 organization to their personal health information, but with their consent, information is  
2 freely transferable to support better medical decision making and a broad range of care  
3 management and quality programs.

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

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

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

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

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

41 In building consensus around a uniform policy, it was necessary to make some hard  
42 choices as well as choices that are inconsistent with some current practices of emerging

1 RHIO organizations. For example, the recommendations do not permit a one time,  
2 multiple organization consent policy, but instead requires each provider organization  
3 and payer organization to obtain consent to access information. Having the accessing  
4 clinician or organization obtain consent will engage the organization in educating  
5 consumers about the consent process. It also will allow consumers to connect the  
6 consent decision to the specific entity to which the consumer is granting access -  
7 whether it is at the office of their primary care physician, their local hospital, a specialty  
8 care provider or at the point in time when they elect to select their health insurance  
9 carrier.

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

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

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

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

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

40 **Limits additional requirements on provider organizations**

41 Understandably, there is significant concern among physicians and hospitals that new  
42 rules not place burdensome obligations or unfunded mandates on clinicians whose

1 main focus is on providing treatment based on the best available information about the  
2 patient. By requiring a simple access consent on a State approved form that covers all  
3 types of health information, the recommended policies adopt a straightforward and  
4 easily implementable solution for provider organizations that mirrors the process already  
5 in place.

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

18

## 19 VI. Next Steps

20  
21 After review of comments submitted in response to this document, the State  
22 Department of Health will issue final policy guidance and take action to include its  
23 recommendations in all future contracts with RHIOs in New York State and inform future  
24 legislative and regulatory proposals. The contract provisions will require RHIOs to:

- 25
- 26 • Adopt privacy policies and procedures consistent with State recommendations;
  - 27 • Use the standardized RHIO consent form approved by New York State to access  
28 identifiable health information via the SHIN-NY governed by a RHIO; and
  - 29 • Participate in a consumer education program initiative launched through the  
30 statewide collaboration process to support the Privacy Policies and Procedures.

31  
32 It is also recognized that further work and ongoing guidance is necessary to ensure the  
33 successful implementation of these standards. The recommended standards seek to  
34 provide specific, implementable policy guidance to RHIOs. Several areas have been  
35 identified in which more process and thought is necessary before specific  
36 recommendations can be put forth. In those instances, further action through a  
37 statewide collaboration process is recommended.

38  
39 New York State is implementing a statewide collaboration process to advance a  
40 governance and policy framework for health information technology initiatives across  
41 the State. The purpose of the statewide collaboration process is to:  
42

- 1     • Providing a convening vehicle for the State and the health care community to  
2       collaborate on key areas of New York's health information technology agenda,  
3       starting with HEAL NY Health IT projects;  
4     • Providing a forum to discuss and collaborate on health IT policy priorities; and  
5     • Coordinating and harmonizing the implementation of regional HIE and quality  
6       and population health IT tools.

7  
8     The New York eHealth Collaborative (NYeC), a NYS not-for-profit corporation is  
9       facilitating the state level collaboration process and providing technical assistance to  
10      HEAL grantees. The Department of Health is participating in the collaboration process  
11      as a public-private partnership. NYeC's mission is to improve health care quality and  
12      efficiency through health IT and is comprised of health care leaders across the State,  
13      including physicians, hospitals, health plans, public health officials, safety net providers,  
14      employers, consumer and health care advocates, quality and regional health  
15      information organizations, and includes participation by health information service  
16      providers (vendors) and health care associations.

17  
18     Among the issues that will require attention through a statewide collaboration process  
19      are:

- 20  
21     • Further definition of "one-to-one" health information exchange;  
22     • Development of consumer education materials and campaign;  
23     • Develop policy guidance to help ensure protection of consumer interests while  
24       facilitating consumer access to and control of their personal health information;  
25     • Consent policies and procedures for use of de-identified data exchanged through  
26       RHIOs, focusing on ensuring adequate protections against reidentification;  
27     • Consent policies and procedures relating to minors; and  
28     • Consent policies and procedures relating to information obtained from federally  
29       qualified alcohol and substance abuse facilities.

30  
31  
**32VII. Acknowledgements**

33  
34  
35     The white paper is a product of the Office of Health Information Technology  
36       Transformation, New York State Department of Health. It is a result of a 2 year  
37       statewide public process comprised of many contributors, including a Steering  
38       Committee, a Legal Committee and multi-stakeholder workgroups.

39  
40     In the last six months, NY HISPC, as part of Phase II, held three stakeholder meetings  
41       to build consensus around a patient consent solution. The meetings were well attended  
42       with participation from diverse stakeholders across the state, including providers,  
43       payers, employers, business leaders, health IT leaders, public health, consumer and  
44       health advocacy representatives, and government, among others.

- 1 A special acknowledgement goes to Tom Check, Visiting Nurse Service of New York,  
2 Rachel Block, United Hospital Fund and Interim Executive Director of NYeC, and Dan  
3 Tietz AIDS Institute, DOH for their facilitation at the stakeholder meetings and to the  
4 panelists who participated in the consensus building process.  
5  
6 The white paper was drafted by a subgroup of the NY HISPC Phase II Team, including:  
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The following organizations participated in the HISPC statewide business practice variations workgroups.

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Albany Memorial Hospital	New York Presbyterian
Anheuser Busch	New York University
Association - Women's Medicine	Northeast Ortho
At Home Care, Inc.	NY Health
Bellevue Hospital	NYC Health & Hospitals Corp.
Bronx RHIO	NYC Health Plan
Brownsville	NYC Health/Hospitals Corporation
Calvary Hospital	NYCLIX
Cayuga Medical Center	NYHQ
Centrex Clinical Labs	NYS Association Healthcare Providers, Inc.
Childrens Health Fund	NYS Association of Health Systems
Community Care Physicians	NYS Clinical Lab
Community Health Center	NYS DOH AIDS Institute
Crystal Run Healthcare	NYSHFA
Department of Corrections	OMH
Excellus Health Plan	Prime Care
Genesee Region Home Care & Hospice	PSSNY
Glens Falls Hospital	Queens Health Network
GNHYA	Revival Healthcare
Greater Rochester RHIO	Rochester Business Alliance
Greenberg Traurig LLC	Saratoga Hospital
Greene County Public Health	Seton Health Systems
Harrison Center Outpatient	St. Ann's Community
Health Care Providers	St. Peter's Hospital
Health First	St. Vincent's Manhattan
Hill Haven Nursing Home	St. Vincent's Medical Center
Hometown Health Center	Staten Island University Hospital
Hospital for Special Surgery	Stony Brook University
IBM	Strong Memorial Hospital
Institute for Urban Family Health	SUNY Stony Brook
Interim Health Care	Syracuse Chamber
IPRO	UB Associates
Kings County Hospital	United Health Services
Kodak	Unlimited Care
Lab Alliance of Central New York	Visiting Nurse Service of New York
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Thomas Buckley	VNA of Albany, Inc.
Michael Burgess	New York State Alliance for Retired Americans
Ann Burnett	NYSDOH - AIDS Institute & Uninsured Care Programs
Rachel Burwell	Cerebral Palsy of the North Country
Blair Butterfield	GE Healthcare
Thomas Carpenter	Affinity Health Plan
Diane Carroll	North Country Children's Clinic
Scott Casler	Lifetime Care
John Cauvel	Next Wave Inc
C. Lynn Chevalier	Health Quest
Nicholas Christiano	Greene County Public Health Nursing Service
Elizabeth Cole	Executive Woods Ambulatory Surgery Center
Ellen Cooper	NBC Universal, Inc
Rick Cotton	CDPHP
William Cromie	Nyack Hospital
Alice Cronin	Medical Society of the State of New York (MSSNY)
Liz Dears	Greene County Public Health Nursing Service
Linda Deyo	NYSDOH
Gregory Dobkins	Rome Memorial Hospital
Maryann Dubai	NYSDOH AIDS Institute
Heather Duell	Kathleen Duffett, RN, JD, Attorney at Law
Kathleen Duffett	Syracuse University
Kevin Dumes	NYeC Board Member
Craig Duncan	Lourdes Hospital
Tom Ellerson	Stony Brook University Medical Center
Simminate Ennever	Manatt Health Solutions
Lori Evans	Our Lady of Mercy Medical Center
Donna Farago	NYSCHP
Debra Feinberg	NYSDOH - Office of Health Insurance Programs
James Figge	Crystal Run Healthcare
Carol Furchak	Southern Tier HealthLink
Christina Galanis	Waiting Room Solutions
Beth Gallo	

Jim Garnham  
Denise Giglio  
Sharon Gonyeau  
Mary Hand  
Ken Harris  
Martin Hickey  
Jeffrey Hirsch  
Susan Huntington  
Matthew Jarman  
Robin Jones  
Annette Kahler  
Mary Kenna  
Brett Kessler  
Al Kinel  
Irene Koch  
Susan Koppenhaver  
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Aileen Martin  
Roberto Martinez, MD  
Joseph Martucci  
Mary Ann McGiel  
David McNally  
John Mills  
George Mina, Jr.  
Lanetta Moore  
Farzad Mostashari  
Betsy Mulvey  
Debra Musser  
Cynthia Nappa  
Carla Novak  
Jeong Oh  
Renee Olmsted  
Katie O'Neill  
Michael Oppenheim  
Johannes Peeters  
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Scott Pidgeon  
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Barbara Radin  
Laurie Radler  
Carol Raphael  
Rita Reynolds  
Cindy Richards  
Salvatore Russo  
John Shaw  
Ben Smith  
Robin Smith  
Joseph Sorrenti  
  
GRIPA  
Visiting Nurse Association of Utica and Oneida County, Inc.  
Cerebral Palsy of the North Country  
Glens Falls Hospital  
NYAHSA - The Center  
Excellus BC/BS  
Waiting Room Solutions  
Glens Falls Hospital  
American Red Cross  
CMIP  
Albany Law School  
Group Health Incorporated  
Bellevue Woman's Hospital  
Kodak  
Maimonides Medical Center  
Eden Park Health Care Center  
Greater Rochester RHIO  
NYSDOH - AIDS Institute  
Seton Health  
Center for Medical Consumers  
Syracuse University College of Law  
Group Health Incorporated  
Visiting Nurse Regional Health Care System of Brooklyn  
Maimonides Medical Center  
Queens Health Network  
North Country Children's Clinic  
CDPHP  
NYS Office of Cyber Security  
Castle Senior Living at Forest Hills  
AARP  
HIP Health Plan  
Canton-Potsdam Hospital  
Phase PiggyBack, Inc.  
New York City Department of Health and Mental Hygiene  
NYHPA  
CVPH Medical Center  
SUNY Upstate Medical University  
Healthcare Association of NYS  
Syracuse University  
Oneida Healthcare Center  
Legal Action Center  
North Shore LIJ Health System  
Tioga County Health Department  
Aurelia Osborn Fox Memorial Hospital  
Palladia, Inc.  
Medical Society of the State of New York (MSSNY)  
The Bronx RHIO  
Montefiore Medical Center  
Visiting Nurse Service of New York  
Memorial Hospital  
Northeast Health  
NYC Health & Hospitals Corporation  
Next Wave Inc.  
Greater Rochester IPA  
ARCHIE  
Interfaith Medical Center

Keith Stack	Alcoholism and Substance Abuse Providers of NYS
Susan Stuard	New York Presbyterian Hospital
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Deborah Tokos	United Health Services
Asha Upadhyay	THINC RHIO, Inc.
Teresa Yennan	Baptist Health
Daniel Walden	Medco Health Solutions
Mary Welch	Trudeau Health Systems
Robert Westlake, Jr MD	NY Chapter, American College of Physicians
John White	Our Lady Of Lourdes Hospital
Dianne Wilson	American Red Cross, New York-Penn Region
Lynn-Marie Wozniak	Next Wave