Health Information Security and Privacy Collaboration

Guidance for Developing Consent Policies for Health IT

Prepared for

RTI International
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Chicago, IL 60606

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Prepared by

Consumer Education and Engagement Collaborative
Colorado, Georgia, Kansas, Massachusetts, New York, Oregon
Washington, West Virginia

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1. INTRODUCTION

This document is intended to provide a framework and guidance to states on developing their own consumer consent policies for participation in health information technology (IT). It is based on the experience of New York State and its work on consent supported by the Health Information Security and Privacy Collaboration (HISPC) initiative. While each state is unique, our hope is that the general considerations and processes used by New York will inform other states as they establish consumer consent policies that address their individual needs.

HISPC is a national initiative funded by the federal Office of the National Coordinator for Health IT (ONC) to address privacy and security variations and challenges related to electronic health information exchange at the state level. New York State has participated in HISPC since its initial phase in 2006. In 2007, during HISPC’s second phase, New York focused on developing consensus based standardized statewide consumer consent policies and forms. In the third phase New York participated in two multistate collaboratives that build on its previous consent work: the Interstate Disclosure and Patient Consent Collaborative, which is examining and addressing differences among states’ consent policies and laws through the utilization of three scenarios of health information exchange modeled after American Health Information Community use cases, and the Consumer Education and Engagement Collaborative, which is developing materials to promote consumer engagement and education about health IT.

This document was developed as part of New York’s participation in the HISPC Consumer Education and Engagement Collaborative. It provides a context for thinking about consent policy as a component of a full range of privacy and security policies, lays out key considerations for states that plan to develop consent policy, and outlines the mechanism by which New York developed its own consent policy so others can adapt it. This document integrates excerpts from several key resources from New York that contain a great deal of additional detail; information on where to find the full versions is included at the end.

New York has benefitted greatly from initiatives and studies on health IT including those by the Markle Foundation’s Connecting for Health collaborative, the California Healthcare Foundation, the American Health Information Management Association (AHIMA), the eHealth Initiative, the Healthcare Information Management Systems Society (HIMSS), the National Alliance for Health Information Technology (NAHIT), the Health Information Security and Privacy Collaboration (HISPC); and the Certification Commission on Healthcare Information Technology’s (CCHIT) work on privacy and security-related product certifications. References to some of these and other resources are included in the footnotes.
Through March 2009, New York’s HISPC team developed educational materials designed to prepare consumers to make informed consent decisions. These materials will also be made available to other states with guidance on how to adapt them for their own use. The materials will be distributed online via http://www.ehealth4ny.org/.

II. CONSENT IN CONTEXT

An essential cornerstone of New York State’s health IT policy is to ensure that consumers are appropriately educated about how their health information can be shared and to provide consumers with the opportunity to decide whether or not they desire to have their information accessible via a statewide network. If consumers are not informed, they have no way of understanding to what they are consenting. Thus, from a consumer trust perspective, new consent policies which clearly define the roles of participants in health IT, coupled with significant provider and patient education programs, are crucial to ensuring that consumers are provided with the opportunity to make informed decisions with respect to with whom and for what purpose their personal health information is shared and used.

How Health IT Affects Consumer Consent

At the most basic level, “consent” in the health IT context refers to policies that give consumers choice about whether and how to make their personal health information available to others electronically. Consent for the electronic sharing of information builds on existing consent policies from a technologically simpler era.¹

Since until now most health information has been in paper form, it has been relatively difficult to share it, regardless of the intended use or the policies that govern that use.

Health IT ushers in a new world by enabling a freer flow of information. It allows health care providers, for the first time, to reach out to large networks of clinicians and providers to see what information is available and use it to aid in an individual’s care.

This brings obvious benefits to the consumer—eliminating the burden of gathering and transporting paper records, avoiding duplicative tests and procedures, and ensuring that their providers have the best information available to make medical decisions and coordinate care. Electronic health information generated through clinical encounters (and potentially stripped of identifying information) can also contribute greatly to research, public health, and quality improvement initiatives.

¹ The Health Insurance Portability and Accountability Act of 1996, known as HIPAA, and the Privacy Rule that implements HIPAA provisions established the first federal baseline for health privacy in the United States. For more on HIPAA and what it requires, see guidance from the US Department of Health and Human Services at http://www.hhs.gov/ocr/privacy/index.html.
In addition to changing the way existing sources of information move, health IT is increasingly enabling consumers to generate and store new information about their health and behavior using patient portals, personal health records, Internet-based platforms, health data banks, and other emerging services and technologies. As consumer creation and control of health content becomes more widespread, consent policies will need to take into account mechanisms for managing consent to use data from these new sources.

While the shift to electronic health information exchange can bring tremendous benefits, it may also heighten risks associated with privacy since there are more potential opportunities for the misuse of data. It is, therefore, essential that consent—and other privacy protections—be carefully reexamined and adapted to function effectively in the emerging world of health IT.

Consent as Part of a Bigger Policy Picture

Privacy concerns and an associated lack of public trust are often cited among the primary barriers to the success of health IT. With a growing number of large-scale and high-profile data breaches in the last several months alone, this is not surprising. For example, in March 2008, a laptop containing personal medical information on 2,500 patients participating in a National Institute of Health cardiac study was stolen from an employee’s car, while in April, 50,000 patient records were improperly accessed at New York Presbyterian Hospital. Medical records belonging to Maria Shriver, Farah Fawcett, George Clooney, and Britney Spears have also been reported as breached recently.

Improper access to health information can have extremely negative ramifications for individuals, including social stigma, discrimination linked to employment, insurance, and financial loans, and even medical identity fraud. In some cases, the fear of misuse of health information leads individuals to avoid seeking the health care they need.

While consent policies are an important tool for empowering consumers and protecting their privacy, they are not on their own sufficient. It is important to view consent policies as part of a broader array of policy protections rooted in Fair Information Practices, which have been developed and used in the United States, Canada, and Europe for more than 20 years to define appropriate ways of handling electronic personal information. Although there are numerous articulations of them, they generally include:

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2 For more on these and other privacy breaches, see the Project HealthDesign blog at http://projecthealthdesign.typepad.com/project_health_design/2008/04/a-banner-month.html.

3 According to a poll by Harris Interactive, one in six adults—representing 38 million people—say they withhold information from their health providers due to fears about how the medical data might be disclosed. Harris Interactive Poll #27, March 2007.

- Notice/Awareness
- Choice/Consent
- Access/Participation
- Integrity/Security
- Enforcement/Remedies

Unfortunately, policy development, which requires a multistakeholder, collaborative process, tends to occur at a slower pace than technical and business developments. Although both Congress and federal agencies are working on nationwide policies concerning health IT, many questions about how to best structure them remain, and the process of answering them will likely take months or years.5

To supplement existing and developing nationwide policies, many states, including New York, have chosen to establish their own health IT policies—on consent and other topics—to respond to their own unique needs. According to a recent Commonwealth Fund report:6

- All states place a high priority on e-health, and nearly 70% of states report “very significant” e-health activities.
- State governors’ highest e-health priorities in the next 2 years are fostering development of electronic health information exchanges and ensuring interconnectivity among health care providers.
- Patient privacy and security of data are among the greatest concerns.
- Almost half of responding states mentioned the challenge of obtaining the trust, buy-in, and participation of health care providers and other stakeholders that are vital to successful adoption.

III. KEY CONSIDERATIONS FOR STATES IN CRAFTING CONSENT POLICY

Individual state approaches to crafting consent and related health IT policies will vary considerably based on factors including states’ size, market characteristics, resources, stage of health IT development, current laws and regulations and demographic profiles. Funding sources are diverse, including state governments, foundations, federal grants, health plans, integrated health systems, and networks of employers. Despite individual variation, there

are several key factors each state should take into consideration in mapping out its policy plans, including its existing health IT model or infrastructure, legal and policy landscape, and overarching governance structure for health IT initiatives.

Among the most comprehensive resources for states (and other entities) that are establishing health information exchange policies (including but not limited to consent) are the Markle Foundation’s *Common Framework* and the eHealth Initiative’s *Connecting Communities Toolkit.*

**Existing Health IT Model/Infrastructure**

States are approaching health IT using a variety of strategies or models. While some, such as New York, have invested heavily in numerous regional health information organizations (RHIOs), others, such as Delaware, have only a single RHIO or none at all. The State of Washington is supporting the Health Record Bank model, while some other states focus on health IT in a specific context, such as e-prescribing. Still others have made relatively little investment in health IT and are not committed to a particular model. An existing health IT infrastructure or commitment to a particular approach may significantly shape a state’s development of consent policy.

In September 2007, New York pledged $105.75 million in state funding to support the implementation of health IT infrastructure. This funding builds on previous rounds for a total investment of over $160 million. New York’s investment in health IT is significant for many reasons, chief among them that it is by far the largest investment of tax dollars in health IT by any state in the United States. From a total investment perspective (including public and private funds), New York is among the top five states in the country.

Underlying New York’s infrastructure and central to its successful implementation are RHIOs—acting as governors or trusted brokers to establish, maintain and enforce privacy and security policies for multiple entities and for multiple purposes. While the term RHIO is not presently defined in federal or state law, RHIOs are defined by the New York State Department of Health as "a non-governmental, multi-stakeholder organization that exists as a New York State not-for-profit corporation to advance interoperable health IT in the public’s interest through a transparent governance structure with an overall mission to improve health care quality and safety and reduce costs." 

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9 See the HEAL 5 request for proposals available at [http://www.nyhealth.gov/funding/ra/0708160258/](http://www.nyhealth.gov/funding/ra/0708160258/).
RHIOs are not technology organizations, do not develop software, and are not proprietary regional health information exchange (HIE) networks. They are regional “exchange organizers or governors” that set policies and ensure adherence to such policies to enable the implementation of New York’s statewide health information network, (called the SHIN-NY, for “Statewide Health Information Network for New York”), and ensure that its components are interoperable.

Before New York began its HISPC-supported work on consent policy, RHIOs across the state were struggling to define what constitutes adequate and meaningful patient consent. Broad variation in opinion existed among stakeholders as to what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy, and what was feasible from an implementation perspective. The state felt that establishing standardized consent policies would help to earn patient trust, provide clarity regarding compliance with New York law, and ensure statewide interoperability.

**Legal and Regulatory Landscape**

An additional precursor to establishing consent policies is a thorough examination of pertinent state laws and, in particular, consideration of how they apply to the existing or proposed health IT model.

New York’s policies that impact health IT are highly fragmented. State law governing health information is spread across dozens of statutory and regulatory provisions. The result is a patchwork of requirements and exceptions that vary greatly depending on the nature of the entity, type of information involved, and purpose of the disclosure.

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

An analysis of New York state law reached the conclusion that under any circumstances, affirmative consent from the patient to exchange health information electronically through the SHIN-NY via a RHIO is required for nonemergency treatment. It also concluded that existing state and federal law provided an insufficient framework for the regulation of RHIOs in New York.
In response, the state chose to develop a cohesive state regulatory framework that applies directly to RHIOs. This framework will include relevant aspects of HIPAA as a floor, and other privacy laws to establish a set of requirements governing the use and disclosure of information, security safeguards, patient access to data, and other matters.  

**Overarching Governance Structure**

States that are developing consent or other health IT policies should consider developing an overarching governance structure that extends beyond those of individual RHIOs or other networks/entities involved in health IT. With its numerous RHIOs, New York felt that a coordinated, state-level governance body was essential to ensure that health IT develops as a public good, without silos or the undue influence of corporate interests. Such a body would serve all stakeholders and their data needs and reduce technology costs and investments for all.

The New York eHealth Collaborative (NYeC, pronounced “nice”) was incorporated in December 2006, and formally designated a public-private partnership by the New York State Department of Health in August 2007. It obtained 501(c)(3) designation in March 2008. It receives strong policy and funding support from the New York State Department of Health. NYeC serves as a focal point for health care stakeholders to build consensus on state health IT policy priorities, and collaborate on state and regional health IT implementation efforts. It straddles the government, health sector, and industry and addresses both public and private priorities.

NYeC works to galvanize health care systems improvement by promoting broad use of interoperable health IT through a comprehensive state policy agenda that:

- Stimulates coordinated and collaborative efforts among health care stakeholders to identify and overcome barriers to widespread health IT adoption and use health IT to enhance evidence-based practice by clinicians and consumer engagement in health maintenance.
- Advances health care performance measurement and public reporting and improvement in patient outcomes.
- Improves public health through effective prevention and management of chronic disease, as well as stronger public health surveillance and emergency response capabilities.
- Ensures accountability by measuring and evaluating health IT’s impact on health care systems, payers, providers, and consumers.

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11 For more on NYeC see the collaborative’s Web site at http://www.nyehealth.org/.
As the coordinating body for New York’s health IT initiatives, NYeC plays an important role in the state’s HISPC work as well as in the facilitation of the statewide collaboration process for state-funded HEAL grants, the federal NHIN trials, and the Health Information Technology Evaluation Collaborative (HITEC), a multi-institutional effort to maximize the impact of health IT projects in New York State through the application of standardized outcome measures and rigorous evaluation methodology.

IV. THE CONSENT POLICY-MAKING PROCESS

Consistent with the key considerations described above, New York State assessed its existing health IT model, studied its legal and regulatory landscape, and developed an overarching governance structure that is inclusive of a wide variety of stakeholders. Within that context, New York was able to establish key principles and a process that would help to evolve those principles into concrete and detailed policy recommendations.

Recognizing Diverse Stakeholder Perspectives

Buy-in from multiple stakeholder groups is important, and throughout the process in New York it was clear that stakeholders approach RHIOs and health IT policy development with a host of pressing needs:

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

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

- **Provider Organizations:** Provider organizations want assurance that additional consent requirements do not impose heavy administrative, technical, and/or financial burdens on their organization and its resources. Such institutions often already have internal information systems and want to ensure that new systems can be implemented in harmony with existing work flow and other requirements related to internal systems.

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• **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, efficiency, affordability, and outcomes. Through a statewide, multi-stakeholder process, health IT strategies are formulated in the public's interest and facilitate a dynamic, bidirectional 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 not be realized without broad-based support from patients, clinicians, providers, payers, and other stakeholders in the health care system.

### Establishing Core Principles

The recommended policies for obtaining consumer consent to exchange personal health information via the SHIN-NY governed by RHIOs were guided by several core principles, summarized below:

- Promote patient-centered care by facilitating consumer choice and addressing consumer concerns about privacy
- Promote exchange of comprehensive information ensuring clinical effectiveness to improve the quality and efficiency of care
- Minimize burdens on health care providers
- Be practical and “implementable” for RHIO participants providing operational flexibility
- Be simple and clear with a concrete rationale
- Foster innovation while ensuring public trust
- Be neutral on technology model
These principles outline the core policy aspirations and practical considerations necessary to implement interoperable health information exchange in New York.

**Holding Stakeholder Meetings**

To engage in a statewide dialogue on consent, New York held three stakeholder meetings in September and October 2007 to identify consent-related issues and gain consensus on a standardized approach. Consumer advocates, health care providers, RHIO executives and clinical leadership, representatives from the NYC Department of Health and Mental Hygiene, and others attended the meetings.

The first meeting was dedicated to understanding the current state of RHIO policy development regarding consent in New York. The second meeting sought to elicit discussion on the key policy questions that a new consent policy for RHIOs would need to address.

At the third meeting, “straw model” recommendations were proposed and discussed. Additionally, at the fourth meeting held in March 2008, an analysis of the “straw model” recommendations were presented and discussed in the form of developed policy recommendations.

A basic outline of the schedule of activities organized by New York is below (Figure 1). It begins in 2007 and extends through 2008.

**Structured Analysis**

The key questions that provided the basis for the consent policy development process are outlined below:

**Activities:** What are the activities with respect to health information exchange we are seeking to govern and support?

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

- Uses of information
- Sensitive information
- Where and at what point consent is obtained
- Standardized consent process
- Durability and revocability
- Consumer engagement
- Audit and transparency
**Benefits/Penalties:** What are the consequences, including benefits and penalties, of meeting the obligations defined above?

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

For each of these key questions, PowerPoint slides were used to structure discussions at the meetings. The slides stated a definition of each issue (for example, corresponding to the first bullet under “Obligations,” above, “Should different uses of information require different standards of consent?”). Next was a set of considerations. In the previous example, considerations included:

- Consumers ultimately have the right to consent to any kind of use. Some uses of information are likely to be more acceptable and predictable to consumers than others (e.g., treatment, payment as they bring direct personal benefit).

- Other uses are less likely to be expected (e.g., research and marketing and may not bring direct personal benefit).

14 These slides are available at [http://www.health.state.ny.us/technology/nyhispc/phase_ii/meetings/3/docs/findings_and_strawman_proposal.pdf](http://www.health.state.ny.us/technology/nyhispc/phase_ii/meetings/3/docs/findings_and_strawman_proposal.pdf).
For unexpected uses, more intensive efforts are necessary to ensure the consumer understands that they are consenting for these uses of health information.

Multiple standards of consent can build patient trust. However, multiple standards will be more burdensome to implement.

Following the initial three stakeholder meetings, the consensus recommendations for consent policy were summarized in a white paper that was posted for public comment, revised, reviewed at an additional meeting, and reposted for public comment in September 2008. One of the themes that emerged in this process was the need to find a mechanism to hold RHIOs—a key element of New York’s health IT strategy—to a standard set of accountability standards. In September 2008, along with the consent white paper, New York issued an additional white paper to examine alternative pathways for ensuring the public accountability of RHIOs, including how an accreditation process could establish a mechanism to define measures for and assess RHIO performance.

Meanwhile, the New York State Department of Health and NYeC continued to develop existing processes into a more formal and structured “Statewide Collaboration Process” (SCP), defined as “a multi-stakeholder effort to develop policies, technical standards, and operational guidance for health IT projects.”

V. CONCLUSION

As of fall 2008, the New York State Department of Health and NYeC were seeking a final round of public comments on their consent policy recommendations white paper. In parallel, through the Statewide Collaboration Process, they are leading the development of a standardized consent form, an operational guidance document, and educational materials for consumers and consumer advocates, as well as a set of policies and procedures for a full range of privacy and security policies, including consent, authorization, authentication, access control, audit, and breach, among other outputs.

17 For more on the HEAL 5 Kickoff meeting, which was the official launch of the Statewide Collaboration Process, see http://www.nyehealth.org/node/68.
19 See http://www.ehealth4ny.org/ for consumer outreach and education materials.
In pursuing its health IT investment program, New York is cognizant that its success will not only be measured by technical, operational, financial, and clinical achievements, but also by the policy framework and rules governing the exchange. The establishment of public trust with respect to the privacy and security of health information is the single most important goal of New York's health IT investment program.

In a very real sense, New York's investment program builds on the collective foundation of numerous outside health IT policy efforts and initiatives and at the same time seeks to go one step further. Because New York is setting policy in the context of live implementations, and is doing so through a statewide public-private collaborative model, it presents a unique opportunity to stress test new concepts which to date have largely been considered in either much smaller settings, on a theoretical basis, or based on proprietary and/or narrow technological approaches. New York's experience should provide all stakeholders a much richer understanding of what works and what doesn't work, and will help to inform and shape emerging state and national policy.

**PRIMARY RESOURCES**

**Resources for Consent in Context**
- “Privacy & Health Information Technology,” slide presentation by Bill Bernstein, Partner, Manatt Health Solutions, April 2008

**Resources for Key Considerations for States in Crafting Consent Policy**

**Resources for the Consent Policy-Making Process**
Materials distributed at the four stakeholder meetings held as part of Phase II of HISPC. Available at http://www.health.state.ny.us/technology/nyhispc/phase_ii/.

See especially the slides from Meeting 3 for findings from previous meetings and a "Straw man" proposal. Available at http://www.health.state.ny.us/technology/nyhispc/phase_ii/meetings/3/docs/finding_s_and_strawman_proposal.pdf


**Other Related Resources**

Materials developed for outreach to consumers and consumer advocates about health information technology will be available in October 2008 at http://www.ehealth4ny.org/.