NEW YORK eHEALTH COLLABORATIVE

STATEWIDE HEALTH INFORMATION NETWORK FOR NEW YORK (SHIN-NY) CONSENT: CONSIDERATIONS FOR THE FUTURE

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SHIN-NY CONSENT WORKGROUP

This white paper reviews and assesses the current SHIN-NY consent framework and outlines three possible approaches to the creation of a new consent framework. Developed by the SHIN-NY Policy Committee for consideration and further discussion by New York State Department of Health.

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EXECUTIVE SUMMARY

Almost a decade ago, a group of providers, patient advocates, insurers, and other healthcare system stakeholders adopted a set of principles to govern the exchange of patient health information through the Regional Health Information Organizations (RHIOs) that comprise the Statewide Health Information Network for New York (SHIN-NY). One of the key principles agreed upon through this process was that, subject to limited exceptions, patient information maintained by a RHIO can be accessed by a RHIO participant only if the patient signs a written consent form authorizing such access. Since the original SHIN-NY consent policy was put in place, a variety of value-based purchasing initiatives, such as the New York's Delivery System Reform Incentive Payment (DSRIP) program, have changed the way in which healthcare organizations seek to access and use patient information. This ongoing transformation of the healthcare system has triggered questions as to whether the current SHIN-NY consent model is fully consistent with the goals of improving clinical care and controlling costs.

To examine this issue, the New York eHealth Collaborative (NYeC) posed a series of questions to a range of SHIN-NY stakeholders. Based on a widely distributed survey and a series of focused interviews, NYeC discovered the following:

- A substantial majority of SHIN-NY participants believe that, from a policy standpoint, the current consent model strikes the appropriate balance between facilitating clinical information sharing and protecting patient privacy. In practice, however, many participants experience workflow problems associated with obtaining patient consent that impede the flow of health information for important clinical purposes.

- The extent of the obstacles faced by SHIN-NY participants is substantially related to the manner in which they seek to use the SHIN-NY. For example, many participants primarily use the SHIN-NY to access the results of laboratory, radiology, and other tests they have ordered. In these cases, the current consent model does not serve as a barrier because participants can rely on the patient's implicit consent for these "one-to-one exchanges" and are not required to obtain a formal written SHIN-NY consent. In contrast, participants that seek to pull a comprehensive history of a patient's medical care from a RHIO face more significant impediments to obtaining consent, especially if they want to access the patient's records in advance of an initial visit.

- Perhaps the greatest obstacles arise in connection with care coordination, quality improvement, and other population health efforts. In these cases, participants seek to obtain information from a broad class of patients, many of whom rarely engage with the healthcare system and are unlikely to have signed a SHIN-NY consent form.

- Technological challenges also complicate the process of obtaining consent. For example, in many hospitals the registrar responsible for collecting consent forms does not have access to the RHIO system to determine whether a patient has previously granted consent to the hospital. This limitation results in duplicative consent requests. The lack of an easily accessible central registry to track consents undermines the efforts of RHIOs to utilize a RHIO-wide consent model under which one participant can obtain consent on behalf of all other participants.

- Patients typically lack familiarity with RHIOs and the SHIN-NY, and are not likely to have a good understanding of the significance of granting or denying consent.

While there are potentially a wide range of options for addressing the concerns reflected in these findings, NYeC identified three primary alternatives to the current consent model for further consideration:

- **SHIN-NY Wide Consent Model** This model is similar to the current model in that it requires the patient to sign a written SHIN-NY consent. But it differs from the current model by allowing patients to sign a single consent form that covers all participants in the SHIN-NY, not just a single participant or all participants in a given RHIO. Under this model, the consent form would not have to list all SHIN-NY participants, but instead, could refer patients to a website where they could view such a list as it changes from time to time.

- **Opt-Out Model** Under this model, a patient's information could be exchanged for all purposes permitted by HIPAA and any other applicable federal laws unless the patient signs a form requesting to opt-out of such exchange. Patients would be notified of their opt-out rights through various means.

- **Flexible Consent Model** This model preserves the current model's requirement for affirmative written consent but creates greater flexibility as to how that consent can be obtained. Currently, only a SHIN-NY-specific written consent is sufficient to authorize access to information through the SHIN-NY. Under a flexible consent model, any consent that covers the purposes for which information will be accessed through the SHIN-NY would qualify as a valid SHIN-NY consent. For example, the broad consent signed by all Medicaid beneficiaries as part of the State's Medicaid enrollment application would be adequate to permit the exchange of their information through the SHIN-NY for the purposes described in that consent.

The current model and the above alternatives are not necessarily mutually exclusive. Given the varying levels of privacy risk associated with different uses of the SHIN-NY, a blended model may be appropriate. For example, an opt-out model could be utilized for patient alerts about inpatient or emergency room discharges that contain limited clinical information while the current model or the SHIN-NY wide consent model could be employed for comprehensive queries for all SHIN-NY records. This approach would facilitate easier access to time-sensitive information about discrete clinical episodes while requiring affirmative consent for more intrusive inquiries into a patient's entire medical history.

Two other key findings emerged through the NYeC review. First, under either the existing consent model or any of the alternative models, improved patient education is essential to make patient choice meaningful. Second, all models should incorporate an on-line mechanism for patients to more conveniently set their consent preferences for the exchange of their information throughout the SHIN-NY.

INTRODUCTION AND METHODOLOGY

This paper examines the following question: does the current SHIN-NY consent model serve as an obstacle to clinically important data exchange among SHIN-NY participants? The current consent model is set forth in the Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State (the SHIN-NY Policies) and the SHIN-NY regulation promulgated by the New York State Department of Health (DOH) in March 2016.

In order to address this question, the paper summarizes the history and current contours of the SHIN-NY consent requirements. The paper also reviews the consent models for health information exchanges in a small sample of other states in order to obtain a better understanding of how the SHIN-NY consent model compares to these models.

As part of its effort to analyze the impact of the current consent model and in conjunction with a group of RHIO, participant, and government agency representatives (the "Consent Workgroup"), NYeC undertook a survey of providers, health plans, RHIOs, and other stakeholders in the healthcare system involved or interested in the SHIN-NY's operation. The survey addressed a variety of topics related to the SHIN-NY and the current consent model, including how participants use information obtained through the RHIOs, how they collect patient consent, and the effect of the consent requirement on the exchange of patient information. NYeC engaged in follow-up interviews with a limited number of survey respondents in order to gain a deeper and more nuanced understanding of their viewpoints.

In addition to the survey and follow-up interviews, NYeC convened a roundtable with experts on New York State privacy law to address the legal basis for the SHIN-NY consent model. The roundtable focused on four discrete questions that are central to the implementation of the SHIN-NY consent model. Officials from DOH and the New York State Office of Mental Health (OMH) attended the roundtable and expressed their agencies' interpretation of various state law privacy provisions. The roundtable aimed to determine which elements of the consent model are required by state law or regulation, and which may be modified without any change in existing legal authorities. In conjunction with the roundtable, NYeC also reviewed applicable state and federal privacy laws.

Based on the survey responses, participant interviews and roundtable, NYeC prepared a summary of the views of SHIN-NY stakeholders about the current consent model. Based on these findings, NYeC developed three primary options for alternatives to the current consent model. After the issuance of this paper, NYeC intends on engaging further with stakeholders to evaluate these options and develop a recommendation that can be presented to DOH and other State officials for consideration.

BACKGROUND ON CURRENT CONSENT MODEL

History of Consent Model

The development of the current SHIN-NY consent model commenced approximately a decade ago. In 2006, the federal Office of the National Coordinator (ONC) established the Health Information Security and Privacy Collaboration (HISPC), a project aimed at assisting states in evaluating their patient consent policies in order to promote the electronic exchange of health information. That year, ONC provided funding to DOH under HISPC. NYeC was established to administer the HISPC initiative on DOH's behalf. NYeC worked to engage stakeholders in the state's healthcare system to assist in the development of the consent model in what became known as the Statewide Collaboration Process (SCP).

Under Phase I of HISPC, DOH, NYeC, and other stakeholders undertook a comprehensive assessment of New York health privacy laws and regulations. In 2007, the participants released the Phase I findings of this initiative. The group concluded that information exchange at the time relied heavily on human judgment exercised in connection with "one-to-one" disclosures between healthcare organizations, and that, to earn patient trust, it was crucial to develop a new patient consent framework for an automated "many-to-many" exchange system.

The second phase of HISPC commenced in July 2007. DOH and NYeC held four stakeholder meetings on patient consent from September 2007 to March 2008. The meetings were attended by consumer advocates, providers, RHIO executives and clinical leaders, DOH representatives, and others involved in the healthcare system. During this period, NYeC, working with other participants in the SCP, produced an initial draft of a white paper on the SHIN-NY consent framework. Based on comments received from SCP participants, a final paper, entitled "Recommendations for Standardized Consumer Consent Policies and Procedures for RHIOs in New York to Advance Interoperable Health Information Exchange to Improve Care," was issued in September 2008. In November 2008, NYeC released the first version of the SHIN-NY Policies.

The 2008 SHIN-NY Policies set out a consent framework that, while refined over time, remains largely intact today. The SHIN-NY Policies established a consent-to-access system under which participants' data is uploaded to the RHIO under a HIPAA business associate agreement and participants are generally required to obtain a patient's consent in order to access that patient's information through the RHIO. Exceptions permitting access without patient consent were established to address certain scenarios such as medical emergencies and public health reporting. The model was designed with the goal that all health information, even sensitive health information that is subject to more restrictive rules, could be accessed through a RHIO if patient consent were obtained.

The white paper recommended that the policies be enforced through contracts between DOH and the RHIOs. It was also suggested that eventually the RHIOs should be accredited in accordance with the SHIN-NY Policies.

NYeC and DOH have continued to fine tune the SHIN-NY Policies in the years since the release of the initial version. However, the core concepts related to consent have not changed since 2008.

Features of the Current Consent Model

Overview of Model

Fundamental to the SHIN-NY consent model is a requirement that participants obtain written patient consent to access patient information through a RHIO. This affirmative consent model differs from consent models developed in some other states, which either do not require patient consent at all or have an opt-out model under which patient consent is presumed in the absence of an express patient request to opt-out of electronic information exchange.

The SHIN-NY relies on a consent-to-access rather than a consent-to-disclose model. Under a consent-to-access model, patient information is uploaded by participants to the RHIO without patient consent under a business associate agreement. However, the data maintained by the RHIO is generally not available to participants until the patient provides consent authorizing the participant to access the patient's information. In contrast, under a consent-to-disclose model the RHIO participant that is the source of the information must obtain the patient's consent to disclose the information to the RHIO and its participants. Once that consent has been obtained and the data is uploaded to the RHIO, other participants may access the data without additional patient consent. The SHIN-NY adopted a consent-to-access model based on the belief that it better promotes information exchange than a consent-to-disclose model because, under a consent-to-access model, the participant that has a motivation to obtain consent—the participant that wants the patient's information—is the one responsible for obtaining consent. In addition, the consent-to-access model ensures that information is uploaded immediately and is available through the RHIO for medical emergencies without patient consent.

Who has Access/Scope of Consent

If a patient signs a consent form that allows a particular participant to access the patient's information, all authorized users of that participant are allowed to access that patient's information. Authorized users are typically the employees or medical staff members of a participant. A patient has no ability to pick and choose which users within that participant will have access to his or her information. User access is controlled by the participant based on standard role-based access protocols.

A patient may pick and choose which RHIO participants have access to his or her information. A patient can agree to allow only one participant access by signing a consent form that applies only to that participant. Alternatively, if the RHIO offers this option, a patient may sign a "community-wide consent" form that grants every participant in a RHIO access. In order to implement a community-wide consent option, a RHIO must maintain a list of its participants on its website and update that list whenever a new participant joins the RHIO. In addition, the SHIN-NY regulations allow a community-wide consent form to apply to organizations that become participants subsequent to the date of the consent only if the RHIO "has documented that it has notified the patient, or the patient has declined the opportunity to receive notice, of the persons or entities becoming [RHIO] participants subsequent to the execution of the written authorization." [1]

[1] 10 NYCRR § 300.5(b)(1)(i)(b).

Exceptions to Consent Requirement

There are limited circumstances in which consent is not required to access a patient's information. No consent is required if the exchange is for public health reporting, disaster tracking, or organ procurement. In addition, providers may access a patient's records in a medical emergency if it is not feasible to obtain the patient's consent for such access.

A special SHIN-NY consent (described below) is not required for a "one-to-one exchange." A one-to-one exchange essentially mirrors the type of exchange that occurs in the paper-based world, where a patient anticipates that providers jointly treating the patient will share information with one another. For example, a physician participates in a one-to-one exchange when the physician receives from a clinical laboratory the results of a test ordered by the physician. One-to-one exchanges are governed by generally applicable New York laws and regulations rather than the SHIN-NY Policies. This means that, in many cases, information may be exchanged based on the patient's oral or implicit consent rather than a formal written SHIN-NY consent.[2]

Consent Form Requirements

The SHIN-NY Policies specify the required elements of a consent form and include a model form that can be utilized by RHIOs and their participants. If a participant does not use the model form, it must use a form that is "substantially similar" to the model that contains specific information. There are two types of consent forms: those for "Level 1" uses and those for "Level 2" uses. Level 1 uses include treatment, care management, quality improvement, and insurance coverage reviews. Level 2 uses are any other uses that do not fall under Level 1 (such as health plan utilization review or research). Both Level 1 and Level 2 forms must provide certain information such as the categories of information that may be disclosed, the intended uses of the information, and the time period during which the consent is to be effective. In addition, Level 2 forms must provide additional information. For example, a Level 2 consent form must indicate a specific date or event upon which the consent expires; there is no such requirement for a Level 1 consent form.

Applicability to Sensitive Health Information

The SHIN-NY consent model is designed to apply to all categories of "sensitive" health information, meaning health information that is subject to heightened privacy protections and consent requirements under the law. New York State law requires consent forms that apply to sensitive health information to specifically reference the type of information being disclosed (for details on state and federal law consent requirements, see Appendix A). The SHIN-NY Policies address these requirements by including in the consent form a notice to patients that HIV, mental health, alcohol and substance abuse, reproductive health, sexually-transmitted disease, and genetic testing information may be exchanged based on the consent.

[2] The SHIN-NY Policies were recently amended to state that a health plan's access to a plan member's medical records for quality improvement or care management purposes may constitute a one-to-one exchange.

Nevertheless, the SHIN-NY Policies may not always be sufficiently robust to allow the exchange of all sensitive health information. For example, as currently interpreted by the federal government, the rules governing certain categories of substance abuse information (set forth in 42 C.F.R. Part 2) require the consent form to name every potential recipient of such substance abuse information. This requirement makes it difficult to use a community-wide consent form to exchange such information, since the consent form must name every potential recipient of information. One RHIO is currently attempting to address this problem by allowing patients to sign a community-wide consent form if a participant presents to the patient a printed list of all RHIO participants at the time of signing. Under this pilot, the community-wide consent only applies to organizations that were participants at the time the consent was signed; if a patient wants to share his or her information with a participant who joins at a later date then the patient must execute a new form.

Consent Models in Other States

While the details differ from state to state, electronic health information exchanges generally utilize one of two patient consent models. The first model is the one used by the SHIN-NY: an opt-in/affirmative consent model that, subject to limited exceptions, requires a patient to sign a written consent form before his or her information may be accessed by exchange participants. The second model is one used by certain other states: an "opt out" model under which patient information is exchanged by participants unless the patient affirmatively requests that his or her information not be shared.[3] Each of these models is described further below.

Opt-out

Nationwide, the opt-out model is most common, with electronic health information exchanges in 38 states and territories utilizing this approach.[4] Under this model, participants in the exchange can share a patient's information without a patient's consent unless the patient opts out of the exchange.

California's statewide health information exchange, called the California Integrated Data Exchange or Cal INDEX, operates under an opt-out model. A patient may opt out by filling out a form online, calling Cal INDEX, or mailing in the opt-out form.[5] Even if a patient opts out, Cal INDEX still retains that patient's information in a database, in which case it can be shared by Cal INDEX only "where required by state or federal law."[6]

[3] There is a third model under which patients do not have the right to opt out, but we do not focus on that model in this white paper because it is not nearly as common as the other models.

[4] NORC at the University of Chicago, Evaluation of the State HIE Cooperative Agreement Program: Final Report (March 2016), *available at* https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf.

[5] https://www.calindex.org/opt-out/

[6] https://www.calindex.org/notice-of-privacy-practices/

Several California laws require patient consent for the exchange of sensitive health information such as HIV test results. As a result, this information is excluded from Cal INDEX.[7] Substance use disorder information protected by 42 C.F.R. Part 2 is also excluded from Cal INDEX because the exchange's opt out model does not meet the Part 2 consent requirements.

The North Carolina Health Information Exchange (NC HIE) also operates under an opt-out model. Unlike the California model, the exchange's enabling statute allows participants to disclose patient information to other participants "for any purpose permitted by HIPAA" notwithstanding any state law or regulation to the contrary.[8] This statute effectively supersedes other more stringent state laws that would otherwise require patient consent for the exchange of sensitive health information through NC HIE. However, the federal Part 2 requirements still apply because the state has no authority to preempt federal rules.

Both the California and North Carolina opt-out approaches present patients with "all-or-nothing" choices. If a patient decides to opt out of the exchange, then no participant can access that patient's information (subject to a North Carolina exception allowing disclosure for emergency treatment and public health purposes). If the patient does not opt-out, then all participants have access to the patient's information. Unlike an opt-in model, there is no means by which a patient can pick and choose which participants may access his or her information and which participants cannot.

Opt-in

Like New York, Massachusetts typically requires affirmative patient consent in order to exchange patient information through the state's health information exchange, called the Massachusetts Health Information Highway (Mass HIway). Because patients generally must give consent, the model complies with state laws that require consent for the exchange of sensitive health information, and therefore sensitive health information—such as that related to mental health, HIV status, and sexually transmitted diseases—is available through the Mass HIway.[9] The Massachusetts model differs from New York's, however, in that it is a consent-to-disclose model, not a consent-to-access model. This means that each participant that seeks to share information through the Mass HIway must obtain the patient's consent to disclose such information to the exchange.[10] Mass HIway also differs from the SHIN-NY in that data generally is not stored with Mass HIway itself. Instead, Mass HIway facilitates the exchange of information directly from one participant to another.[11]

[7] https://www.calindex.org/opt-out/

[8] N.C. Gen. Stat. § 90-413.5(c).

[9] See, e.g.., Atrius Health Mass HIway Consent, *available at* http://www.masshiway.net/HPP/cs/groups/hpp/documents/document/c2vu/df9m/~edisp/atrius_consent_form.pdf.

[10] See Mass HIway, Consent Policy Statement, *available at* http://www.masshiway.net/HPP/cs/groups/hpp/documents/document/c3rh/dgvt/~edisp/consent_policy_statement.pdf.

[11] See Massachusetts Executive Office of Health and Human Services, the Massachusetts Health Information Highway, *available at* http://www.mass.gov/eohhs/gov/commissions-and-initiatives/masshiway/

The consent models in these four states are summarized in the table below.

State	Basic Model	Data uploaded even if no consent or an opt-out?	If patient has consented/ not opted out, can patient choose which providers may access the patient's data?	Exchange allowed even if no consent or opt-out in some circumstances?	Is sensitive health information protected by state law included?
California	Opt-out	Yes	No	Only if required by state or federal law	Excluded
Massachusetts	Consent to disclose	No	Yes	Yes for public health	Included
New York	Consent to access	Yes	Yes	Yes for emergencies, public health purposes, disaster tracking, and organ procurement	Included
North Carolina	Opt-out	Yes	No	Yes for emergencies and public health purposes	Included; state laws are preempted

FINDINGS

Consent Survey and Interviews

In order to gain a better understanding of how SHIN-NY participants obtain consent and the impact of the consent process on information exchange, NYeC conducted a survey on the SHIN-NY consent process in June and July of 2016. NYeC received 359 completed responses to the surveys. Most respondents were providers, with hospitals, physicians' offices, clinics, and mental health/substance abuse programs being the most common respondents. Health plans accounted for 8% of respondents. The respondents were geographically dispersed throughout the state. Approximately 62% of respondents identified themselves as being participants in a RHIO, with the remaining either not participating or unsure of their status. A more detailed analysis of the survey results can be found at Appendix B. To enhance the insights gained from the survey results, NYeC conducted follow-up interviews with six RHIO participants with a focus on participants involved in the DSRIP program.[12]

Patient Contact and Education

The survey results showed that RHIO participants typically assign responsibility to non-clinical staff for educating patients about RHIOs and the RHIO consent form. Thirty-seven percent of respondents indicated that a registrar typically discusses the RHIO with patients, and 41% said this was a responsibility of a receptionist; others identified an officer manager, secretary, or medical records assistant as performing this task. Some respondents stated that clinical staff engaged in these discussions as well: Twenty-nine percent said nurses talked with patients about RHIOs and 17% said physicians engaged in these conversations.

Nearly half of respondents—45%—indicated that their patients rarely or never ask questions about the RHIO. Twenty-nine percent said patients sometimes ask questions about the RHIO and 12% said patients always or often ask questions, with the remainder of respondents unsure. The fact that so many respondents said that their patients have little curiosity about RHIOs could mean that many of these patients simply do not understand what RHIOs are, what functions they perform, and how their activities might be beneficial or present risks to the patient. Follow-up interviews underscored these results, with respondents saying that their patients typically did not have many questions about the RHIOs.

The vast majority—85% of respondents—said they educate patients about RHIOs through in person discussions. Fifty-four percent said they provide pamphlets or other written materials to patients about RHIOs. Some also discuss RHIOs over the telephone. Less than three percent of respondents said they provide an online course or training on RHIOs, and less than two percent said they notify their patients about online resources describing RHIOs.

[12] Respondents who participated in follow-up interviews consisted of the Monroe Plan (health plan, IPA, and health home), Oscar health insurance (health plan), NYU Langone Medical Center (hospital and PPS), Maimonides Medical Center (hospital, PPS, and health home), Fort Drum Regional Health Planning Organization (PPS), and Millennium Collaborative Care (PPS).

Impact of Consent Requirements

When asked about the appropriateness and impact of the SHIN-NY patient consent model, 75% of respondents who are RHIO participants said the requirement strikes the appropriate balance between patient privacy and the clinical needs of healthcare organizations. Twenty-three percent said the consent requirement was too strict, with only 1.5% stating it is too lenient. Standing alone, these responses suggest that, at least in theory, there is relatively broad support for the current consent model from a policy standpoint.

However, in subsequent questions, respondents expressed concerns about the practical implications of implementing the current model. Fifty-five percent of respondents said the requirement to obtain consent always, often, or sometimes prevents their organizations from obtaining patient information that could be used to deliver medical care. Forty-five percent said that the consent requirement always, often, or sometimes prevents their organization from sharing information with another organization seeking to provide patient care.

In explaining why the consent requirement sometimes interferes with information exchange and optimal patient care, respondents often cited workflow issues. For example, 28% said their staff already had too many duties and did not have time to manage the consent process. Nine percent said their staff was not adequately trained to obtain informed consent and 8.5% said it was too difficult to track which patients had granted consent. Five percent said obtaining patient consent was too time consuming.

Many respondents indicated that the response of some patients to the SHIN-NY consent form is a barrier to exchange. Eighteen percent said that patients find the form confusing. Nineteen percent said that patients often refuse to grant consent. However, declining to grant consent arguably is not a failure of the current model; rather, it shows that patients are exercising their right to choose as whether their information should be shared.

In a follow-up discussion, one hospital respondent noted that consent rules can interfere with access to patient information in emergency settings. Although the SHIN-NY Policies allow for participants to "break the glass" and access patient information in an emergency even when there is no patient consent for such access, the respondent noted that it accessed the RHIO through a certified application, a means by which a participant can access information through the RHIO through the participant's own interface. The respondent said, however, that it was difficult to set up a break the glass framework through their certified application, and thus they typically did not view information in the RHIO in emergency situations.

Barriers to Care Coordination

Many respondents cited difficulties in making timely contact with patients as a concern with the current consent model. Twenty-five percent said their organization often needed access to a patient's health information prior to the patient's first visit, when such organizations would have an opportunity to seek consent from the patient. Thirteen and one-half percent said their organization often lacked direct contact with patients, making it difficult to obtain consent.

In follow up interviews, RHIO participants made clear that the consent requirement was primarily an issue in regards to care coordination/care management. Obstacles to care management were of particular concern in the context of the DSRIP program, value-based purchasing initiatives, and other reform efforts that often rely on the combination of higher quality information and improved care management as a means of improving care while reducing cost.

One health insurer that participates in Medicaid managed care explained that it often aims to reach out to a member within 24 hours of that member's treatment in an emergency room and connect that member to primary care services. This protocol is based on evidence suggesting that individuals are more receptive to obtaining primary care shortly after a visit to the emergency room. The insurer noted, though, that it often does not learn of an emergency room visit until weeks or months later when the hospital submits a claim for such care. The insurer said it would like to receive alerts from the RHIO every time a member is admitted to an emergency room, but right now it can only receive alerts for members who have granted them consent, which represents a minority of their membership. Moreover, the insurer said it was not practical to ask their entire membership for consent. As an insurer, they lack face-to-face contact with their members, so the insurer indicated that their only option is to send out a large mailing to their members asking for consent, which would likely be ignored by most of their members.

Another insurer cited the same issue and discussed its attempt at solving the problem. That insurer gives its enrollees the option of communicating with the insurer and receiving materials through a web-portal. Enrollees who select that option are given the opportunity to sign an online consent form giving the insurer access to the patient's information through a RHIO. The insurer estimated that about 75% of its enrollees who interact via the web portal choose to sign the RHIO consent, and that a majority of its enrollees overall sign such a consent. However, the insurer noted that there are still gaps, as many of their enrollees either do not have the opportunity to provide consent online or decline to grant consent.

A hospital acting as the lead of a PPS under the DSRIP program noted a similar problem. Under DSRIP, thousands of patients are attributed to that hospital, and many of those patients have never received care at the hospital. The hospital and its PPS partners had performed an analysis of data made available to them suggesting that certain individuals were at a high risk of requiring additional medical services. Like the health insurer, the hospital was interested in obtaining alerts on these patients whenever they were treated in an emergency room. But since these patients had not been treated at the hospital and therefore had not consented to the hospital having access to their information, the alerts could not be sent. The hospital questioned the feasibility of obtaining written consent from all patients attributed to its PPS under DSRIP as a means of accessing these alerts.

Another PPS explained that its physicians use the SHIN-NY primarily to receive the results of laboratory, radiology, and other tests ordered by the physician. The SHIN-NY works well for this purpose because the physician relies on the patient's implicit consent and does not have to obtain a signed SHIN-NY consent form. This PPS indicated that few providers in its network pull community-wide clinical data through the SHIN-NY. The lack of interest in in this type of use is largely the result of concerns about the reliability of the information and the resistance of staff to going outside the electronic health record into a different system to retrieve data. It is unclear whether consent would be a barrier if these problems were solved. The PPS stated that, when asked, almost all patients give consent. PPS providers are considering seeking consent to receive alerts. The main problem created by the consent requirement is that it is an obstacle to population health activities because it is impossible to search the SHIN-NY for high-risk patients who do not regularly engage with the healthcare system.

Alternatives Proposed by Respondents

One question in the survey was open ended and gave respondents an opportunity to provide suggestions as to how barriers to more effective use of the RHIOs could be minimized. Responses to this question are summarized below.

Multiple respondents said that patients were being asked to sign too many consent forms and that it was important to reduce the number of forms to reduce patient confusion and participant burden. One noted that certain healthcare programs—such as DSRIP and Health Homes—have their own consent forms that differ from the RHIO forms. The respondent suggested these forms be combined into one form. Others suggested that a more universal SHIN-NY consent form be used, rather than having forms being limited to participants in specific RHIOs. Similar comments were made in follow up interviews. One participant said that some patients live in areas where multiple RHIOs operate, so developing a state-wide consent form would reduce the number of consents that these patients have to sign. One hospital representative said that some patients assume that when they say "yes" they are granting access to all participants, not just one, and that the SHIN-NY should be able to operationalize a more universal consent. That representative said obtaining multiple consents was a particular burden on smaller practices that lacked sophisticated electronic infrastructure to keep track of consents.

A number of respondents recommended switching to an opt-out system, stating that the current requirement to obtain consent for patient consent was too difficult to operationalize. Some also voiced support for an opt-out system in follow up interviews.

Others made suggestions regarding patient education. One suggested the development of statewide educational materials such as brochures, videos, and FAQs. Another suggested the development of a brief educational course describing the SHIN-NY that could be presented to patients before they sign a consent form. One respondent recommended the development of public service announcements about the RHIO. Some respondents said that the participants themselves also needed more training on the SHIN-NY.

Some suggestions did not address consent policies but recommended technological changes to improve the functioning of the RHIOs. A common suggestion was to allow participants to access the RHIO through their own EHRs, thereby reducing the time it takes a user to access patient records. Some suggested that patients should be able to provide consent online.

Consent Law Roundtable

On June 30, 2016, NYeC hosted a roundtable with attorneys and other experts on New York and federal healthcare privacy laws. A list of attendees can be found at Appendix C. The roundtable focused on four discrete questions with important ramifications for the operation of the SHIN-NY in New York State.

The group first addressed the question of whether New York State law requires patient consent for the exchange of patient-identifiable health information when patient consent is not required by HIPAA (e.g., when the disclosure is for treatment, payment or healthcare operations) and no specially protected class of sensitive information (such as HIV or mental health information) is involved. A representative of the DOH Office of Legal Counsel stated that patient consent is required under these circumstances, based on New York Education Law Section 6530(23)[13] and state other statutes and regulations. Other roundtable participants noted that the Education Law section and many of other state statutory or regulatory provisions state that disclosure of patient information without patient consent is permitted if "authorized by law." These participants suggested that HIPAA granted the necessary authorization. The DOH representative responded that HIPAA did not "authorize" unconsented disclosures under these provisions since HIPAA was not intended to change the underlying framework of state law.

Proceeding based on the assumption that some form of consent is required for disclosures for treatment purposes, the group addressed ways of how the consent process could be operationalized efficiently. Roundtable participants observed that previous state guidance supported the principle that implicit or oral consent can be sufficient. One participant suggested that if a patient is given notice that his or her information will be shared through a RHIO and is informed of a right to opt-out, that patient's decision not to opt-out could be viewed as implicit consent to allow the exchange of health information. Other participants questioned this view.

There was also discussion about using different consent models for different types of disclosures. While written consent is required to exchange some types of sensitive health information, it was suggested that a two-tier system could be developed under which alerts lacking detailed medical information could be sent out based on implicit patient consent and more detailed clinical information would be accessible only if a patient provides written consent.

The roundtable participants next turned to the question of whether New York law allows providers to exchange a patient's HIV information without formal written consent of the patient. The DOH representative stated that DOH has interpreted a provision of the Public Health Law—which allows exchange without written consent in cases where "knowledge of the HIV related information is necessary to provide appropriate care or treatment to the protected individual"—to allow providers to share such information in all cases where the provider is treating the individual since HIV status is always relevant to treatment.[14] The DOH representative explained that the phrase "necessary to provide appropriate care or treatment" also applies to care management activities but does not cover quality improvement, since quality improvement does not target individual patients. While this interpretation eliminates the need to obtain written consent in many situations, some roundtable participants pointed out that the requirement to obtain consent in another form (be it implicit or oral) would still apply to HIV information. Some expressed doubts as to whether RHIOs would be willing to assume that providers had obtained such consent, particularly in regards to sensitive health information such as HIV status.

[13] N.Y. Educ. Law § 6530(23) states that it is professional misconduct for a physician, physician's assistant or a specialist's assistant to "reveal personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law."

[14] N.Y. Pub. Health Law § 2782(1)(d).

The discussion next moved to mental health information. While New York law typically requires written patent consent to exchange information held by providers regulated by OMH or the Office for People with Developmental Disabilities (OPWDD), written consent is not required if information is exchanged "between facilities and managed care organizations, behavioral health organizations, health homes, or other entities authorized by [OMH or OPWDD] or the department of health to provide, arrange for, or coordinate healthcare services for such patients or clients who are enrolled in or receiving services from such organizations or entities."[15] An OMH representative explained that the reference to "other entities" was not intended to cover every organization licensed by DOH, OMH, or OPWDD, but was instead limited to organizations that these agencies specifically authorized to share mental health information pursuant to this statutory provision. The OMH representative indicated that such a list was still being developed and guidance on how this provision would be applied to PPSs participating in the DSRIP program would be issued at a later date. A DOH representative pointed out that primary care providers often take a lead role in providing mental health treatment, and that the new statutory provision did not apply to such individual practitioners engaging in care coordination.

Finally, the group considered whether state health information privacy laws should be liberalized so that more information could be exchanged for purposes permitted by HIPAA without obtaining patient consent. Some participants contended that the current consent requirement should remain in place. One participant noted that it is important to many patients that they have the right to decide whether their information can be shared, and this is particularly important in the case of sensitive health information since some patients will quit treatment if they believe their information is widely accessible. Other participants recommended a different approach. One participant argued that having patients sign a form is generally not meaningful consent, and that there are better means of achieving privacy goals.

Interpretation of Findings

It is difficult to distill the various viewpoints of SHIN-NY stakeholders into a single position about the impact of the current consent model on information exchange. The current model draws mixed reviews from the RHIOs, healthcare organizations, and government officials that must implement it on a day-to-day basis. On the one hand, a significant majority of survey respondents indicated that the current model strikes the right balance between supporting clinical goals and protecting patient privacy. And certain participants stated that other data exchange barriers—such as the workflow burdens associated with having to access another system external to the provider's electronic health record and provider concerns about the accuracy and usefulness of the available data—were threshold problems that have to be resolved even if a different consent model were adopted. On the other hand, the survey results suggest that many RHIO participants occasionally or regularly fail to exchange patient information due to the obstacles associated with obtaining patient consent. In some cases, this is the result of the inability to obtain patient consent in advance of a visit or procedure, when it would be helpful to retrieve relevant information. In other cases, it is workflow issues—such as staff simply being too busy to discuss the consent form with patients—that can create the barrier to information sharing.

[15] N.Y. Mental Hygiene Law § 33.13(d).

One important point that emerged from the stakeholder input is that the impact of the current consent model varies significantly with the manner in which a SHIN-NY participant seeks to access and use patient information. In particular:

- **Pushing Test Results.** Many healthcare providers rely on the SHIN-NY primarily as a means of receiving laboratory, imaging, or other test results ordered by the provider. In this use case involving the "pushing" of data to the accessing provider, the SHIN-NY consent requirement does not pose a barrier to information exchange because the provider may rely on the exception in the SHIN-NY Policies covering "one-to-one" exchange, which permits the provider to obtain the patient's implicit or oral consent under existing New York law, without having to obtain a written SHIN-NY consent from the patient.

- **Pulling Community-Wide Information.** Providers who seek to "pull" data broadly from the SHIN-NY rarely encounter patients who decline to give consent, but these providers face staffing and workflow burdens of varying severity associated with explaining the form and managing the consent process. These burdens are usually insurmountable if the provider wants to access the patient's information in advance of a visit, procedure, or admission. However, some providers are reluctant to pull data from the SHIN-NY for clinical reasons that are unrelated to the consent requirement.

- **Receiving Alerts.** There is a strong interest among many providers in receiving "alerts" from the SHIN-NY about important clinical events involving their patients, such as an emergency room visit or an admission to the hospital. The current consent model restricts the ability of providers to receive alerts in cases where an event triggering an alert occurs prior to a patient visit with the provider seeking access to such alert.

- **Engaging in Population Health Activities.** It appears that the greatest obstacles created by the current consent model arise in connection with population health activities conducted by insurers, individual providers, or multi-provider ventures such as PPSs and Accountable Care Organizations (ACOs). In these use cases, the healthcare organization often seeks to pull comprehensive data about a large cohort of patients to identify those who may be underutilizing the healthcare system or otherwise receiving sub-optimal care. Since many of these patients are disengaged from the system, it is often difficult to obtain their consent.

Another important theme is that technological limitations can sometimes interfere with the consent process. While only 8.5% of survey respondents cited the difficulty of tracking patient consents as a barrier to information exchange, this is likely a reflection of the fact that participants still largely rely on a "single-consent" model: that is, each participant typically obtains consents that grant access only to that participant and not other RHIO participants. In follow-up discussions some noted that the lack of a statewide system for tracking which patients have granted consent to which participants is an issue in cases where patients sign consent forms that apply to multiple participants, such as under a community-wide consent model. Some advocated for the creation of a statewide consent management system, although one PPS contended that such a system would not help because consent would still have to be obtained from millions of patients statewide and participants would still have to spend time checking to see if patients had granted consent. Relatedly, some cited the lack of an online portal where patients can grant consent as an issue.

POTENTIAL ALTERNATIVE PATIENT CONSENT MODELS

There are a wide range of alternative consent models that could conceivably be implemented to address the constellation of clinical and operational issues raised by the current SHIN-NY consent requirements. Moreover, a single model may not be the only option; a patchwork of models that establishes different rules for different use cases may also be possible. To focus the evaluation of the many possible alternatives to the current consent model, we consider three options below: (1) a SHIN-NY wide consent model; (2) an opt-out model; and (3) a flexible consent model. We also discuss how these models might be blended to address different use cases.

SHIN-NY Wide Consent Model

A theme that emerged in the surveys and post-survey discussions is the problem of "consent overload." Patients often are being asked to sign a RHIO consent form for every RHIO participant they visit. While the adoption of a community-wide consent model by some RHIOs has helped mitigate the impact of this problem, the model has not provided a comprehensive solution. Patients who receive care under the DSRIP program or through Health Homes also must sign forms that allow access to their information under these programs. And if a patient resides in an area where multiple RHIOs operate, the patient may have to sign consent forms for different RHIOs. Moreover, since it is often difficult to keep track of who signed a consent form and who did not, patients are often asked to sign consent forms over and over again.

In order to address this issue, a "SHIN-NY wide" consent form could be developed. This form would give a patient the option of granting access to every participant in every RHIO in New York State who is treating the patient. Patients who are interested in having their information shared among all participants in the state would therefore have an option of allowing this to occur by signing just one document. In theory, the consent could be combined with consents used by other programs. For example, the Health Home consent form could contain two options: one which allows only the Health Home itself to access the patient's information through the RHIOs, and a second which grants such access to all SHIN-NY participants.

The potential benefits and disadvantages of a SHIN-NY wide consent model are described in the chart below.

Benefits and Disadvantages of SHIN-NY Wide Consent Model

Potential Benefits	***Reduced patient confusion:*** If implemented correctly, the SHIN-NY wide consent model would reduce "consent overload" and would lead to fewer consent forms being signed. This could help reduce patient confusion. ***Reduced burden on participants:*** Participants could reduce the time spent on obtaining patient consent. In many cases, participants would not need to obtain a consent form at all, since patients would have already signed a SHIN-NY wide consent. ***Improved ability to engage in care coordination:*** Currently, organizations seeking to coordinate a patient's care often cannot obtain that patient's information through a RHIO because those organizations have never previously interacted with the patient. Under a SHIN-NY wide consent model, those organizations could access information from all patients who signed a SHIN-NY wide consent. ***Preservation of patient choice:*** A SHIN-NY wide model still requires patients to sign a written consent to allow the exchange of their information through RHIOs. Thus, patients who object to the sharing of their information can easily prevent such sharing by declining to sign a consent form.
Potential Disadvantages	***Need for system of tracking consents:*** The SHIN-NY wide consent model can only work if there is a statewide system for tracking patient consents and making tracking information available to staff who are responsible for obtaining consent. If an effective system of tracking consent is not developed, then participants will be forced to obtain consent in cases where a patient has already granted consent, and the SHIN-NY wide model will produce little benefit. ***Continuation of workflow problems:*** The SHIN-NY wide consent model could reduce the number of consents that participants need to obtain. However, the model would not eliminate workflow problems stemming from the requirement to obtain patient consent. Participants would still need to have a process for obtaining consent from their patients, and therefore staff would still need to be trained on the operation of RHIOs. ***Exclusion of Part 2 information:*** The SHIN-NY wide consent model does not conform with current Part 2 requirements. While it is possible that Substance Abuse and Mental Health Services Administration (SAMHSA) may liberalize these requirements, Part 2 information may still need to be treated differently than other health information. Depending on the content of the final version of the pending Part 2 rules, in order to operationalize this model, it may be necessary for RHIOs to flag providers who are subject to Part 2 and treat such information differently from other information. One potential solution is to use a SHIN-NY wide consent for non-Part 2 participants only, and adopt a separate, consent-to-upload that would be used by Part 2 participants.

In theory, a SHIN-NY wide consent could be implemented without any legislative action since there do not appear to be any state laws that expressly prohibit such a model. Nevertheless, legislation could be useful in clarifying that the model complies with state law, and would prevent any interpretations of state laws that would interfere with the model's implementation.[16] Moreover, the SHIN-NY regulations could be interpreted to require RHIOs to provide written notice to patients who have signed a community-wide or SHIN-NY wide consent form whenever new participants join the RHIO or SHIN-NY.[17] A new statute could address the notice and any other implementation issues in a manner that better facilitates the development of such a model.

Opt-Out Model

The current consent model is premised on the idea that patients should grant affirmative written consent in order for their information to be shared through RHIOs, subject to limited exceptions such as emergency medical situations. Many other states, however, have not accepted this basic premise. Instead, these states employ an opt-out model under which patient information may be exchanged even without written consent. Instead, patients must affirmatively choose to opt-out in order to prevent their information from being shared among health information exchange participants.

While a SHIN-NY wide consent likely could be implemented without a statutory change, an opt-out model directly conflicts with several New York statutes. The Mental Hygiene Law, for example, generally requires written patient consent in order for facilities and programs regulated by OMH or OPWDD to exchange patient information. Moreover, DOH has interpreted New York State law to require patient consent in nearly all circumstances, although it need not be written and may be implicit. Thus, a new SHIN-NY data privacy statute would be required to override these existing laws and allow an opt-out system for the SHIN-NY.

[16] For example, the HIV law states that a "general authorization" cannot be used as form that allows the sharing of HIV records.

[17] 10 NYCRR § 300.5(b)(1)(i)(*b*).

The potential benefits and disadvantages of an opt-out model are described in the chart below.

Benefits and Disadvantages of Opt- Out Model

Potential Benefits	***Reduced provider burden:*** An opt-out model has the potential to significantly alleviate the burden imposed on RHIO participants. RHIO participants would no longer be obligated to obtain consent to access their patients' health information via the SHIN-NY. ***Increased use of the SHIN-NY:*** With a lower administrative burden, RHIO participants may choose to use information available in the SHIN-NY more frequently. This in turn could lead to higher quality care for patients. ***Improved ability to engage in care coordination and population health:*** Organizations that provide care coordination or population health services would no longer have to wait until a patient specifically granted consent. Instead, these organizations could receive alerts or data about all patients for whom they are responsible, except those patients who choose to opt out.
Potential Disadvantages	***Privacy impact:*** Under an opt-out model, information disclosure would be the default for every patient in the state. Inevitably, some patients who would prefer that their information be kept private may not know about the opt-out model or the existence of RHIOs at all. Even if a vigorous public education campaign occurs, inevitably participants will exchange the information of at least some patients who would not have consented to such exchange had they known about it. ***Legislative change:*** An out-out model can only be accomplished through legislative change, which may be difficult to achieve. ***Part 2 information:*** An opt-out model does not comply with Part 2. Moreover, since Part 2 is based on a federal statute that requires written consent for the sharing of substance use disorder information, an opt-out model will continue to conflict with Part 2 absent a change in federal law. A change permitting an opt-out model is highly unlikely. It will thus be important to properly identify Part 2 information, keep it segregated from other information available in the SHIN-NY, and subject such information to a separate consent process. ***Tracking opt-outs:*** A system would need to be developed that would prevent a patient's information from being shared if a patient opted out.

Flexible Consent Model

A flexible consent model would require the patient's affirmative written consent for information exchange but loosen the requirements as to the form of that consent. In particular, the flexible consent model would allow participants to access data through the SHIN-NY without obtaining a specific SHIN-NY consent if they obtained a broad consent from the patient in another context. Participants who had not obtained such a consent could continue to use the SHIN-NY consent form.

A broad consent that is sufficient to cover all of the typical uses of information accessed through the SHIN-NY is already provided by certain individuals. For example, upon enrolling in the Medicaid fee-for-service program or a Medicaid managed care plan, a Medicaid beneficiary must agree to the release of medical information under a number of circumstances. Those circumstances are broadly worded and include the release of information by providers "as reasonably necessary for my health plan or my providers to carry out treatment, payment, or healthcare operations."[18] There is nothing in this consent form that restricts the manner in which the beneficiary's information is exchanged for these purposes. Thus, the Medicaid enrollment form consent would appear to be legally sufficient to permit the exchange of all Medicaid beneficiaries' information through the SHIN-NY. [19]

Potentially, similarly broad consents could be obtained in other contexts for patients not covered by Medicaid. For example, the model policy forms developed by the Department of Financial Services (DFS) for commercial insurers include a provision under which enrollees authorize their healthcare providers to share medical information with the insurer for plan administration purposes and authorize the insurer to share such information with third parties helping to administer the plan. That language could conceivably be relied upon by insurers to access their enrollees' information through the SHIN-NY. The provision could also be broadened to cover the exchange of information between providers participating in the SHIN-NY. This broader authority could be subject to an opt-out, where the enrollee checks a box on the insurance enrollment form to limit access for plan administrative functions, as reflected in the current model DFS policy form.

These alternative paths for obtaining consent could integrate the consent process into existing workflows. This approach could substantially reduce the number of patients who had to be asked by their providers to sign a SHIN-NY-specific consent.

In addition, a flexible consent model could reduce the need to obtain consent across different programs. One consent form could apply not only to the SHIN-NY but also to the DSRIP and Health Home programs, among others. This could help reduce consent overload for patients and participants and thus confusion regarding the consent process.

The SHIN-NY Policies would need to be revised in order implement a flexible consent model. Currently, the SHIN-NY Policies require the use of a particular DOH-approved form—the Authorization for Access to Patient Information Through a Health Information Exchange Organization—which directly references exchange through a RHIO, or a form that is "substantially similar" to such form. These alternative consent forms, such as the consent on the Medicaid enrollment form, are not substantially similar to the DOH-approved form and therefore do not comply with the SHIN-NY Policies.

[18] Access NY Health Care Health Insurance Application, at 8, *available at* https://www.health.ny.gov/forms/doh-4220all.pdf.

[19] While some might express concern about Medicaid beneficiaries being required to grant this consent as a condition of receiving health benefits, this requirement has been in place for many years.

The benefits and disadvantages of a flexible consent model are described in the chart below.

Benefits and Disadvantages of a Flexible Consent Model

Potential Benefits	***Reduced provider burden:*** RHIO participants would have to obtain consent less frequently, since they could often rely on consents collected by other entities (such as Medicaid). ***Increased use of the SHIN-NY:*** As with the opt-out model, a lower administrative burden on RHIO participants may cause those participants to use information available in the SHIN-NY more frequently. ***Improved ability to engage in care coordination and population health:*** Like the other models, the flexible consent model could help promote care coordination, since it would be easier for RHIO participants to rely on consents obtained by other organizations.
Potential Disadvantages	***Reduced patient understanding of data sharing:*** Under the current model, an individual must sign a consent that is a stand-alone document and specifically explains the unique data sharing systems established by RHIOs. The flexible consent model would allow providers, health plans, and other organizations to share information through a RHIO based on consents that are combined with other documents and lack the same level of detail as the SHIN-NY form. As a result, some patients may have a reduced understanding of the nature and scope of the information sharing to which they have consented. ***Reduced patient choice:*** It is not clear whether Medicaid beneficiaries could obtain benefits without consenting to make their information available through the SHIN-NY. ***Part 2 information:*** A flexible consent model does not currently comply with Part 2 requirements, since forms like the Medicaid enrollment form lack information required by Part 2. While SAMHSA is in the process of revising the Part 2 rules, it is unlikely that the final form of such rules will allow the use of a flexible consent model. As with the other models, a potential solution is to use a separate consent-to-upload for Part 2 providers only. ***Tracking consent:*** As with the other models, a flexible consent model would require an improved system of tracking consents.

Blended Models

The descriptions above are not intended to suggest that one consent model must necessarily apply to all uses of information in the SHIN-NY. It is possible that the consent model could vary depending on how information is being accessed.

For example, the survey results and follow-up interviews suggest that the current consent model is not a barrier in regards to the sharing of laboratory, imaging, or other test results with ordering physicians, since these physicians treat such transmissions as "one-to-one" exchanges that may occur based on the patient's implicit consent rather than a formal written consent. Thus, there appears to be no need to change the current consent model to support the continued use of the SHIN-NY for this purpose.

In contrast, providers expressed frustration that the current consent model often poses challenges in receiving timely alerts about the discharge of patients from the inpatient unit of a hospital or an emergency room. In these cases, a timely alert is critical to optimal follow-up care, but there is no scheduled patient visit during which the provider may obtain consent. Moreover, while these alerts serve an important clinical function, they involve the disclosure of only a limited set of data about a discrete event. Thus, in balancing clinical objectives against privacy concerns, there may be a reasonable case for permitting alerts based on an opt-out model.

The case for an opt-out model might be considerably weaker, though, when a participant seeks to access a patient's entire medical history through a RHIO. In that scenario, there may be less urgency associated with the disclosure (e.g., the provider could wait until the patient visit to obtain consent even though having the records pulled in advance might be convenient) and the range of medical information being accessed is potentially quite broad. In this case, the balance between clinical and privacy considerations may tilt in favor of affirmative consent, through either the current model or the SHIN-NY wide consent model.

The state legislature, in fact, has already moved towards a blended model in regards to information maintained by OMH and OPWDD licensed providers. The general rule is that such providers need written patient consent in order to share patient information, unless an exception applies.[20] However, written consent is not required if information is being exchanged "between facilities and managed care organizations, behavioral health organizations, health homes, or other entities authorized by the department or the department of health to provide, arrange for, or coordinate healthcare services for such patients or clients who are enrolled in or receiving services from such organizations or entities."[21] Thus, the recently amended statute appears to exempt certain care coordination activities from the standard consent requirement.

[20] Mental Hygiene Law § 33.13(c)(7).

[21] Mental Hygiene Law § 33.13(d).

Other Consent Reform Considerations

In addition to reconsidering the underlying consent model, stakeholders need to address two other issues directly relevant to the effectiveness of the consent management process. reforms related to consent.

Consent Management

As noted above, the ability to keep track of which patients have granted consent is a concern for some respondents. Currently, a participant often can find out whether a patient has granted a consent covering that participant by logging into a RHIO and searching for that patient. However, this system creates certain obstacles. Generally, it is an office administrator or registrar who is charged with obtaining consent from a patient, not the clinician who views the patient's information in a RHIO. However, it can be time consuming for the non-clinician to log into a RHIO's system for the sole purpose of finding a patient and determining whether he or she has previously granted consent. Thus, rather than doing so, staff often review only their own records to determine whether a patient has granted consent. In addition, since consent information is held by each RHIO independently, a participant that wants to know whether a patient has granted consent via any RHIO would need to sign into each RHIO one-by-one, an extremely time consuming task that is not practical.

In a model where each participant obtains a consent that applies only to that participant and no others, this system is potentially workable, since participants will generally have their own internal records as to whether patients have granted consent and therefore need not rely on information held by RHIOs. But in a community-wide or SHIN-NY wide model, this system breaks down because each participant does not have a simple means of determining whether another participant has obtained a community-wide or SHIN-NY wide consent.

Therefore, the development of a statewide electronic consent management system could help address certain problems related to the consent process. Such a system could only work if consent information could be easily obtained. Ideally, this would mean that a patient's consent status would automatically appear in the participant's EHR relating to that patient.[20] A push from the state could help with the development of such technology, although some EHR vendors have already worked to establish fields containing consent values. In addition, such a system would have to contain information about consents obtained from every RHIO in the state.

Ideally, such a system would allow patients themselves to go online and input their consent choices. Patients are far more likely to utilize this option if they can set their consent preferences in connection with viewing their own health information through a patient portal. Currently, a statewide SHIN-NY patient portal is not yet operational. But if such a portal is launched as planned in 2017, then patients will have a compelling reason to interact with the SHIN-NY on-line. They will also be able to see the type of information that can be exchanged through the SHIN-NY and will have a better sense of the costs and benefits of allowing such an exchange. Taken together, these changes will make patients more motivated to actively manage their consent preferences.

While an improved consent management system seems essential to the SHIN-NY wide consent model, it may also be necessary to implementing an opt-out model. In an opt-out model, RHIOs must have a means of ensuring that participants do not access the information of patients who opt out. One means of doing so is the creation of centralized electronic registry that can be accessed by participants that would indicate which patients have opted out.

Patient Education

The consent survey conducted in connection with the preparation of this white paper did not include patients. But the survey suggests that, at least from the provider standpoint, patient understanding of RHIOs is low. Only 12% of respondents reported that their patients often or always had questions about RHIOs. This feedback is aligned with anecdotal evidence in which few RHIO participants report engaging in extensive discussions with their patients about the RHIO. Patients are making an important decision about the use of their own health information, yet they typically do not discuss that decision at all with the providers, health plans, and other entities charged with carrying out that decision. It seems likely that many patients do not understand the decision they are making, and that many are simply signing a consent form (or declining to sign) with little awareness of the ramifications of that decision.[22]

A patient education campaign can help address this lack of understanding. While all RHIOs maintain websites and some offer materials that help educate patients, there has been no ongoing statewide education campaign aimed at improving patient understanding of RHIOs. New York State could fund the development of materials that could be widely distributed to patients at doctor's offices and other locations where patients grant consent. The campaign could target patients at the time that they would be most receptive to receiving such information; that is, when they are presented with a consent form and have to make a choice as to whether or not to sign.

An educational campaign would be particularly important if a SHIN-NY wide consent were to be adopted. Such a consent would give patients the power to allow the exchange of their information among all RHIO participants in New York State by signing just one form. Patients would need to understand the difference between the SHIN-NY wide consent option and the more traditional option under which patients grant consent to only one participant at a time.

Patient education also would be a critical component of an opt-out model. If the SHIN-NY switched to an opt-out model and patients were unaware of the change, then privacy concerns would be substantial, since patients would not have a meaningful opportunity to opt-out.

In order to undertake an effective campaign, state funds likely would need to be allocated to promote patient education. This could entail substantial up-front costs. Moreover, these costs would continue as patients who turn 18 and newcomers to New York State would also need to be informed of their right to opt-out.

[22] Of course, in some cases patients may not have questions simply because they agree with the principle of information sharing and do not have concerns about the manner in which it is done.

RECOMMENDED NEXT STEPS

Following a review by the SHIN-NY Policy Committee and the NYeC Board of Directors, the paper will be presented to the Department of Health and the Governor's office. The research conducted by leadership at NYeC, DOH, and the Consent Workgroup has provided an evidence base that gives policy makers a better understanding of how SHIN-NY Participants view the current consent process. Participants hold the key to improving the on-going work to transform healthcare in New York State. Efforts to improve the systems that support that transformation work should incorporate a process to identify what potential changes in the SHIN-NY consent process, if any, will best help improve healthcare services delivery and especially care management.

We recommend that, concurrently with the state's review, the SHIN-NY Consent Workgroup, which has reviewed and contributed to this report, be reconvened and charged with developing fast track recommendations for any changes to the SHIN-NY consent model based on the report's findings. The Workgroup would also be charged with developing a set of analytic "measures" to enable the priorities that emerged from the White Paper to be objectively scored and queued up for on-boarding. Such an analysis would include consideration of all or some of the following attributes of each of the priorities for change:

1. **Importance.** How important is it to facilitating and supporting efforts of healthcare transformation efforts in New York State?
2. **Strength of Consensus.** How much agreement is there on benefit and need of each priority among key participants and other stakeholders, such as relevant state programs (DSRIP, PPS, etc.), state agencies (DOH, OMH, OHIP, etc.) and the RHIOs?
3. **"Shovel Readiness".** Will it require regulatory or statutory change? Does it harmonize with existing state and federal requirements?
4. **Operational Readiness.** Can it be folded into current workflows with minimal effort or not?
5. **Technological Readiness.** Is it dependent on technologies that are readily available, currently in the pipeline, already in the planning stage, or being discussed for the future?
6. **Cost Factors.** What are the estimated costs to stakeholders associated with the change and who will bear the costs?
7. **Patient Engagement.** Does it improve patient engagement both in the consent process and in their healthcare outcomes?
8. **Patient Privacy.** Does it permit protection of patient privacy to the degree required by federal and state law?
9. **Participant Adoption.** Does it encourage or inhibit participant use of information in the SHIN-NY?

We recommend that the SHIN-NY Consent Workgroup focus on the three primary alternatives that are outlined in this report: (1) a SHIN-NY wide consent model; (2) an opt-out model; and (3) a flexible consent model in the context of the priorities that emerged from the research. In doing so, the Workgroup can evaluate the potential combination of models, for example, an opt-out model for alerts but the continuation of an affirmative consent model for other use cases. We also recommend that the Workgroup consider other issues related to consent management, such as:

- The development of a statewide mechanism for tracking patient consents.
- The ability of patients to grant/revoke consent through an online portal.
- Patient education efforts, including the sharing of best practices for patient education among RHIOs and their participants as well as investigation of successful education programs in other states.
- The development of technology allowing users to access RHIOs through their participant's electronic health record system.
- The development of technology that improves the ability to segment Part 2 and other sensitive health information from other forms of patient information.
- The sharing of best practices for staff training related to consent.
- The simplification of language in the current consent form.

We further recommend that the Workgroup consider which proposals can be implemented in the short-term, medium-term, and long-term. For example, RHIOs and their participants sharing best practices on staff training regarding consent could be embarked upon almost immediately, while establishing a state-wide "registry" of patient consent status would take more time.

The Workgroup should take into account both the findings of this report and any other information that is deemed relevant, such as the experiences of RHIOs in experimenting different consent models. Based on this analysis, the Workgroup can make specific proposals on how the SHIN-NY consent process can be improved so as to best support healthcare transformation in New York State.

APPENDIX A: SUMMARY OF APPLICABLE PRIVACY LAW

Federal Law

HIPAA

Under HIPAA, covered entities—providers, health plans, and healthcare clearinghouses—may use and disclose health-related information that identifies an individual, referred to as "protected health information," for many day-to-day operational purposes. Although HIPAA requires covered entities to obtain a patient's signed authorization for certain types of disclosures, with one limited caveat noted below, HIPAA contains a broad exception that allows covered entities to exchange information for purposes of treatment, payment, or healthcare operations (the ability to exchange information for healthcare operations is subject to the limitation that only the minimum necessary information be disclosed and both parties have a relationship with the patient).[23] "Healthcare operations" include quality improvement and case management, among other activities.[24] Subject to the minimum necessary rule, protected health information may also be exchanged without patient authorization for payment purposes, which includes billing and collecting payment. Since exchanges of information through the SHIN-NY typically are undertaken for purposes of treatment, payment, or healthcare operations, HIPAA generally does not require patient authorization for these exchanges.

The one exception to this rule is that a covered entity must obtain a patient's authorization in order to disclose psychotherapy notes, even if the disclosure is made to another healthcare provider for treatment purposes.[25] However, given that SHIN-NY participants do not seek to share psychotherapy notes through the SHIN-NY, this rule is not a barrier to the exchange of information through the SHIN-NY.

[23] 45 C.F.R. § 164.506.

[24] 45 C.F.R. § 164.501.

[25] 45 C.F.R. § 164.508(a)(2).

42 C.F.R. Part 2

The federal Confidentiality of Alcohol and Drug Abuse Patient Records regulations (codified at 42 C.F.R. Part 2) have an important impact on information exchange through the SHIN-NY. Unlike HIPAA, which applies to nearly all healthcare providers and health plans, Part 2 governs only "federally assisted alcohol and drug abuse treatment programs." Thus, in order to be subject to Part 2, a provider must be both a "program" and "federally assisted." To be considered an alcohol or drug abuse treatment "program," an individual or entity must "hold[] itself out as providing, and provide[], alcohol, or drug abuse diagnosis, treatment, or referral for treatment."[26] This generally means that a clinic, residential center, or inpatient facility specially licensed by the state to provide substance use disorder treatment, or any other organization that publicly describes itself as a substance use disorder treatment provider, is a "program." In contrast, a typical medical practice or a general hospital is not a "program" even if it provides substance use diagnosis or treatment services on a periodic basis.

While the definition of the term "program" is fairly narrow, the definition of "federal assistance" is quite broad; it includes any entity that receives federal funds, has a tax exempt status, or maintains a license issued by a federal agency, such as certification by Medicare or registration to dispense controlled substances.[27] As a result, the vast majority of "programs" are subject to Part 2.

Part 2, in contrast to HIPAA, generally does not allow providers to share Part 2 information without patient consent for purposes of treatment, payment, or healthcare operations. Instead, Part 2 requires such programs to obtain the patient's consent for these types of information sharing. There are a few limited exceptions to the consent requirement, the most significant of which covers disclosures in medical emergencies.

Part 2 also imposes detailed rules on the form of patient consent. The consent form must include a general description of the program or person making the disclosure, the purpose of the disclosure, and the kind of information being disclosed. Importantly, the consent form must also list "[t]he name or title of the individual or the name of the organization to which disclosure is to be made."[28] SAMHSA has interpreted this provision to mean that the consent form cannot reference a class of providers—such as all providers who treat the patient—and, instead, must specifically name each provider authorized to receive patient information. SAMHSA has further indicated that the list of potential recipients must be included within the text of the consent form itself or on a printed attachment to that form. Accordingly, if a consent form indicates that information may be shared with all providers who are listed on a particular website, the form violates the Part 2 rules because the names of the providers are not listed on the form itself.[29] This rule effectively prohibits RHIOs from including Part 2 providers in a system of community-wide or SHIN-NY wide consent, where the form generally references all RHIO providers.

[26] 42 C.F.R. § 2.11.

[27] 42 C.F.R. § 2.12(b).

[28] 42 C.F.R. § 2.31(a).

[29] SAMHSA, "Applying the Substance Abuse Confidentiality Regulations, Q16" (Apr. 28, 2015), *available at* http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs; and SAMHSA, "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange, Q18," *available at* http://archive.samhsa.gov/healthPrivacy/docs/EHR-FAQs.pdf.

In a proposed rule issued on February 9, 2016, SAMHSA proposes to modify this rule, stating that "an entity that facilitates the exchange of health information" should be allowed to share substance use disorder information with providers who provide treatment to the patient even if the consent form only contains a "general designation" of the recipients.[30] This change, by itself, would appear to allow the use of a community-wide or SHIN-NY wide consent model. However, SAMHSA also proposes stricter requirements relating to Part 2 consent forms. In particular, SAMHSA proposes that the consent form must list the names of all Part 2 programs that are sharing information. If this proposal were finalized, it would at the very least require Part 2 programs to obtain a "consent to disclose" in addition to any other consents already obtained by SHIN-NY participants. The comment period for the proposed rule ended several months ago and comments are currently under review by SAMHSA. It is unclear when the proposed rule will be finalized and which changes to the current rule it will contain.

New York State Law

General Consent Requirement

Several provisions in New York State law generally address the concept of privacy of patient-identifiable health information:

- Education Law § 6530(23), which applies to physicians, physician's assistants, and specialist's assistants, states that "revealing of personally identifiable facts, data, or information obtained in a professional capacity without the prior consent of the patient, except as authorized or required by law" constitutes professional misconduct.
- Public Health Law § 18(6) states: "Whenever a healthcare provider, as otherwise authorized by law, discloses patient information to a person or entity other than the subject of such information or to other qualified persons, either a copy of the subject's written authorization shall be added to the patient information or the name and address of such third party and a notation of the purpose for the disclosure shall be indicated in the file or record of such subject's patient information maintained by the provider…" The provision goes on to say that: "Any disclosure made pursuant to this section shall be limited to that information necessary in light of the reason for disclosure. Information so disclosed should be kept confidential by the party receiving such information and the limitations on such disclosure in this section shall apply to such party."
- Public Health Law § 2803-c(3)(f) states: "Every patient shall have the right to have privacy in treatment and in caring for personal needs, confidentiality in the treatment of personal and medical records, and security in storing personal possessions."

State officials have cited these provisions as the basis for the State's position that New York law requires patient consent for the exchange of patient identifiable information. Courts have found that Public Health Law § 18(6) can be violated in cases where an organization shares a patient's information with a third party without the patient's consent. However, courts have not addressed whether any of the provisions cited above are violated in cases where the disclosure is made for purposes of treatment, payment, or healthcare operations as allowed under HIPAA.[31]

[30] 81 Fed. Reg. 6988 (Feb. 9, 2016).

[31] *Caraveo v. Nielsen Media Research, Inc.* 01 CIV 9609, 2003 WL 169767 (S.D.N.Y. Jan. 22, 2003); *Rockland Cnty. Patrolmen's Benevolent Assoc., Inc. v. Collins*, 225 A.D.2d 534 (N.Y. App. Div. 1996).

HIV Information

Public Health Law § 2782(1) states "No person who obtains confidential HIV related information in the course of providing any health or social service or pursuant to a release of confidential HIV related information may disclose or be compelled to disclose such information" except under a limited number of circumstances. One exception allows for disclosure to "a healthcare provider or health facility when knowledge of the HIV related information is necessary to provide appropriate care or treatment to the protected individual, a child of the individual, a contact of the protected individual, or a person authorized to consent to healthcare for such a contact…." In addition, disclosure may be made to "third party reimbursers or their agents to the extent necessary to reimburse healthcare providers for health services."

Disclosure of HIV related information may also be made to "any person to whom disclosure is authorized pursuant to a release of confidential HIV related information." Unlike most of other provisions of New York state privacy law, the HIV law specifies what must be in the written release. In particular, the release must include the following statement, or language which is substantially similar to such statement: "This information has been disclosed to you from confidential records which are protected by state law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further disclosure in violation of state law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is NOT sufficient authorization for further disclosure." [32]

Providers Regulated by OMH or OPWDD

The Mental Hygiene Law provides privacy protection for records maintained by "facilities," which are defined to include providers who have been issued an operating certificate by, have entered into a contract with, or receive funding from OMH or OPWDD.[33] Private mental health practitioners or other medical providers who do not fall within this definition are not subject to this provision. Patient identifiable information maintained by such facilities "shall not be released by the offices or its facilities to any person or agency outside of the offices" except pursuant to a limited number of exceptions. One exception allows information to be released "with the consent of the patient or client or of someone authorized to act on the patient's or client's behalf, to persons and entities who have a demonstrable need for such information and who have obtained such consent, provided that disclosure will not reasonably be expected to be detrimental to the patient, client or another…." Mental Hygiene Law § 33.13(c)(7).

Thus, there is no general treatment exception under the Mental Hygiene Law, and typically licensed mental health providers must obtain the written consent of a patient in order to share that patient's information. However, the mental hygiene provision allows the exchange of patient identifiable information without written consent "between facilities and managed care organizations, behavioral health organizations, health homes, or other entities authorized by the department or the department of health to provide, arrange for, or coordinate healthcare services for such patients or clients who are enrolled in or receiving services from such organizations or entities." Mental Hygiene Law § 33.13(d). This new provision, which was adopted in 2016, is intended to make it easier for Health Homes and other entities involved in care coordination to obtain information from OMH and OPWDD regulated providers in order to coordinate patient care.

[32] N.Y. Public Health Law § 2782(5)(a).

[33] N.Y. Mental Hygiene Law §§ 1.03(6), 33.13(a).

Substance Use Disorder Information

Mental Hygiene Law § 22.05(b) states: "All records of identity, diagnosis, prognosis, or treatment in connection with a person's receipt of chemical dependence services shall be confidential and shall be released only in accordance with applicable provisions of the public health law, any other state law, federal law, and duly executed court orders." The applicability of the provision is somewhat unclear: the language cited above suggests it applies any provider in New York State that provides chemical dependence services (even if it is a solo practitioner practicing privately in an office) but the provision appears in an article that addresses the admission of patients to substance use disorder facilities or programs, and thus arguably may apply only to such facilities and programs. Regardless, this section states that substance use disorder information may be released in accordance with other state and federal law, and therefore it does not appear to apply more broadly than 42 C.F.R. Part 2.

Records of Genetic Tests

Civil Rights Law § 79-l(3)(a) states: "All records, findings, and results of any genetic test performed on any person shall be deemed confidential and shall not be disclosed without the written informed consent of the person to whom such genetic test relates. This information shall not be released to any person or organization not specifically authorized by the individual subject of the test." The provision requires a patient's written consent when disclosing "records, findings, and results" of a genetic test. However, it is not clear whether written patient consent is needed if an organization wishes to disclose the fact that a genetic test was performed on an individual but not disclose the actual results of the test. Further, the meaning of the term "specifically authorized" is unclear. It is possible that this term could require the consent form to list the names of all recipients of the genetic test information, in effect mirroring the consent form requirement under 42 C.F.R. Part 2.

Abortions

General Business Law § 394-e(1) states: "It shall be unlawful for any person, firm, or corporation doing business in this state to furnish a report of a referral for abortional services or a report of an inquiry or request therefor, to any person or government agency unless such person, firm, or corporation has reasonable grounds to believe that the person or government agency requesting the report is (a) a law enforcement agency, or (b) the state department of health or the department of health of the city of New York, or (c) authorized in writing by the subject of such report, or (d) unless such person, firm, or corporation shall have been ordered to furnish such report by a duly constituted court having jurisdiction to issue such an order." Although the statute speaks of referrals for and inquiries about abortions, it could reasonably be interpreted to apply to records relating to any abortion related services. In that case, the statute appears to require written patient consent for the exchange of such information, except in a limited number of cases that are not typically relevant to the treatment of patients.

Information Held by HMOs

Public Health Law § 4410(2) states: "Unless the patient waives the right of confidentiality, a health maintenance organization or its comprehensive health services plan shall not be allowed to disclose any information which was acquired by such organization or plan in the course of the rendering to a patient of professional services by a person authorized to practice medicine, registered professional nursing, licensed practical nursing, or dentistry, and which was necessary to acquire to enable such person to act in that capacity, except as may be otherwise required by law."

Minor Consent Information

Most New York State health privacy laws address the issue of whether consent is required to exchange patient information and, if so, what form such consent must take. In the case of certain services provided to minors, state law raises an additional question: who, exactly, must provide the consent?

Typically, when a minor (an individual under the age of 18) receives a healthcare service, it is the minor's parent or guardian, not the minor, who consents to such services.[34] However, under New York State law there are certain categories of services which are subject to the consent of the minor. These services are often referred to "minor consent services." Minor consent services include services related to the treatment of sexually transmitted diseases, prenatal care, mental health care, substance use disorder care, and HIV testing.[35] Similarly, the United States Supreme Court has interpreted the United States Constitution to give minors the right to consent to contraception and abortions. In addition, any services provided to emancipated minors—which include minors who are parents or are married—are services which require the consent of such minors.[36]

In cases where a minor but not the parent consents to a service provided to the minor, New York law often explicitly provides that such information cannot be shared with the parent.[37] In contrast, New York law is less clear as to whether minor consent information can be shared with a provider in case where the parent, and not the minor, has granted consent to the exchange of the minor's health information (although the HIV statute does say that a release allowing disclosure of confidential HIV information must be signed "by the protected individual, or if the protected individual lacks capacity to consent, a person authorized pursuant to law to consent to healthcare for the individual.")[38] For this reason, the SHIN-NY regulation allows participants to exchange minor consent information so long as doing so complies with federal law and the minor is not a parent, married, or otherwise emancipated.[39]

[34] *See Alfonso v. Fernandez*, 606 N.Y.S. 2d 259, 262 (App. Div. 2d Dep't 1993) (recognizing the common law rule requirement parental consent for the provisions of health services to a minor).

[35] *See* N.Y. Pub. Health Law § 2305(2) (sexually transmitted diseases); N.Y. Pub. Health Law § 2504(3) (prenatal care); N.Y. Mental Hyg. Law § 33.21(c) (mental health); N.Y. Mental Hyg. Law § 22.11(c) (substance use disorder); N.Y. Pub. Health Law §§ 2780(5), 2871 (HIV tests).

[36] N.Y. Pub. Health Law § 2504(2).

[37] *See*, e.g., N.Y. Pub. Health Law § 17 ("[R]ecords concerning the treatment of an infant patient for venereal disease or the performance of an abortion operation upon such infant patient shall not be released or in any manner be made available to the parent or guardian of such infant.").

[38] N.Y. Pub. Health Law § 2780(9).

[39] 10 NYCRR § 300.5(b)(3)(i).

APPENDIX B: DETAILED CONSENT SURVEY RESULTS

The SHIN-NY Consent Survey was launched on Survey Monkey on June 20th and was active for approximately one month, closing on July 25th. There were 359 completed responses to the survey that came from 278 unique locations. Responses came predominantly from hospitals (23.4%), physicians' offices (27.3%), clinics (15.32%), and mental health clinics (15.32%) for a total of 81% of the responses. Other categories included: nursing facilities (11%), multi-practice organizations (13%), public health agencies (4%), FQHCs (2%), pharmacies (5%), and health plans (8%).

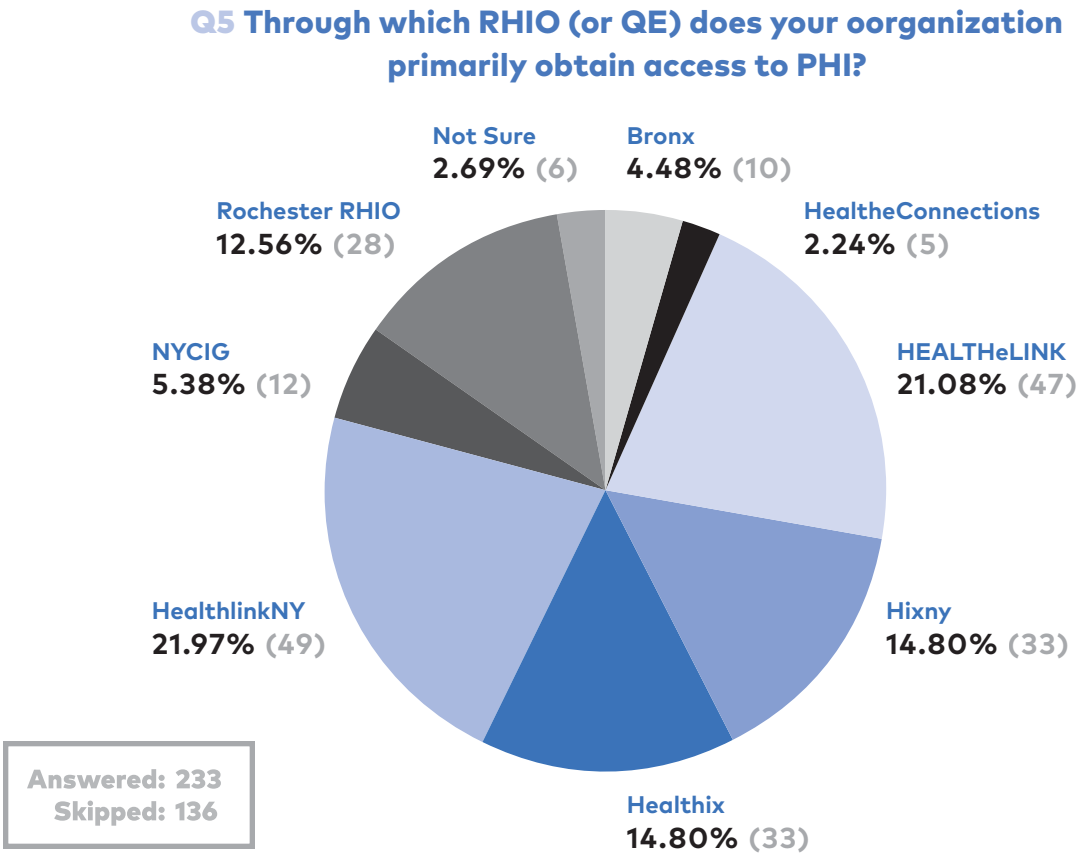
The geographic spread of the survey respondents were evaluated with respect to the RHIO regional distributions and demonstrated an applicable response across the state. There were two respondents from out of state, one from Vermont and one from Susquehanna, Pennsylvania. HealthlinkNY and Hixny region had higher uptake in respondents to the survey based on geography.

Category	Unique organizations responding to the survey	Total in State
Hospitals	63	205
FQHC	7	57
Health Plans	23	45

Question 4 split the survey in two directions. Participants completing the survey who are connected to a RHIO completed 21 additional questions. Respondents not connected to a RHIO or were not certain if they were connected completed 4 additional questions that aided in evaluating the usefulness of data in the HIE and barriers that may exist to connecting to the SHIN-NY. Of the 359 responses, 223 answered "yes" and proceeded to provide answers to the additional 21 clarifying questions on consent while 136 answered "Not Sure" or "No" and provided responses to the 4 additional questions.

Of the 136 respondents that answered "Not Sure" or "No", it was verified through practice name and IP address that 24 are participating in a RHIO. This demonstrates that 7% of the respondents had limited understanding of their organization with respect to the SHIN-NY and connectivity. There were a total of 15 responses from public health agencies and their answers were evaluated on each question to ensure their lack of consent requirements did not affect the data collected. The respondents answered appropriately as "N/A" or "other" in the majority of questions, minimizing their effects on the survey.

QUESTION 5 - QUESTION 25 WERE COMPLETED BY THE 223 RESPONDING "YES" TO Q4



Question 6, 7, and 8 were used to ascertain the number of staff that have access, are regularly using Protected Health Information (PHI) through a RHIO, and the perceived usefulness of the available PHI. Of the 223 respondents, approximately half have more than 20 staff with access to the RHIO, 27% have five or less staff, and the remaining 27% have between six and 20 staff with access. Of those with access, 78% of the respondents indicated that less than 50% of those with access, regularly access PHI on a weekly basis. Less than 4% of the respondents indicated that the PHI was not useful with the rest indicating a variety of usefulness.

Protected Health Information Types and Access Points

The next set of questions was used to determine when and for what purposes PHI is accessed, and what information is most useful. For hospitals, PHI was most frequently accessed in emergency department and outpatient department settings. Of the options presented, organizations predominantly access PHI when care coordination and care management is required (56%), prior to or during an office visit (48%), and during a patient emergency situation (36%). When organizations do access PHI they are primarily accessing laboratory results and patient discharge summaries followed by patient alerts related to a patient's inpatient admission.

Seeking and Managing Consent

Questions 12 through 17 helped asses where in the organizations' work flow consent was requested, managed, and how education on consent was provided. 77% of respondents indicated that consent was requested at the patient's first visit. 49% of the 77% of respondents indicated that if consent was not on file the patient was asked to consent at every visit. 85% of respondents indicated that getting patient consent was mostly performed in person. 87% said that it was performed by either a receptionist or a registrar. 28% indicated that care managers secured patient consent and another 28% said that consent was gotten by nurses. 40% of respondents indicated that there were sometimes questions by patients about the RHIO. The main themes of these questions were:

- What is a RHIO and what does it do?
- What is consent, and what organizations have access to a patients PHI?

Approximately 50% of the 223 responses were in each of these four categories. Education on RHIOs was provided in person and through pamphlets or other written materials.

Questions 18 and 19 provided insight and suggestions on improving consent enrollee activities to make the process better lessening the burden to an organization.

The next set of three questions was aimed at determining how organizations characterized the consent requirement and whether the requirement prevented access to or the sharing of PHI. Although 75% of the respondents indicated that the requirement strikes the appropriate balance, the same group of respondents determined that the requirement prevented the access and sharing of PHI as shown in the table below (close to 50% of the responses). When looking at the three questions grouped together it demonstrated that the responses to the first question may not have been as comprehensive of a single statement as intended.

Characterize Consent Requirement		**Prevents access to PHI**		**Prevents sharing of PHI**	
It is too strict.	23.4%	Yes	93%	Yes	86%
		No	7%	No	14%
It strikes the appropriate balance.	75.1%	Yes	55%	Yes	47%
		No	45%	No	53%
It is too lenient.	1.5%	Yes	33%	Yes	33%
		No	67%	No	67%

Questions 23 and 24 attempted to determine what and where the issues/barriers were to participating in HIE for organizations already working with a RHIO. Likewise, question 27 asked about the barriers for organizations NOT yet working with a RHIO. Four distinct categories were discovered:

1. Work Flow (Including time requirements),

2. Access and Usage (Including data quality and perceived usefulness of the data in the RHIO. For those organizations not working with a RHIO this also includes cost),

3. Patient Reluctance to Provide Consent (Training & Education for Patients and Staff), and

4. Concerns with Security.

Of the four categories, the two primary areas focused on work flow and access and usage.

	Q23: Why is patient consent requirement problematic?	Q24: What are barriers to use of PHI available in RHIOs?	Q27: What are barriers to accessing PHI through a RHIO?
Work Flow	176	130	26
Access and Usage	18	172	76
Patient Reluctance	95	0	10
Security Concerns	0	6	12
No issues	89	70	29

One question in the survey provided for an open-ended response designed to gather direct feedback from the participants currently working with a RHIO. The question asked for suggestions that might help minimize the consent barriers they identified. 52% of respondents indicated they had no suggestions. 5% suggested improvements to RHIO functionality and 10% of respondents suggested increasing the number of participants so as to increase the amount of usable information in the RHIO. (Neither of these themed responses were supportive of the question on consent and were removed from the table below). Of those responses in this section that did address consent, four distinct categories emerged. The percentages below reflect these suggestions.

Category	Percentage
Change to Opt-Out	14%
Allow for Community-Wide Consent—consent once	7%
Simplify the forms and the process for the patient, suggestions for online consent choices	45%
SSO—EMR integration—Simplifying the process for the provider	20%
Training—For patients, providers, and staff	18%
Mental health consent issues	3%

The final questions aimed at respondents that DO NOT currently have a connection with a RHIO were used to assess the perceived usefulness of PHI and the other avenues where electronic PHI may be attained. More than 81% of the respondents felt access to electronic PHI was important, while less than 4% perceived it to be not important. 38% of responses indicated that they obtain electronic PHI from other sources, and those sources included:

Response	Percentage
Private HIE	12%
Direct exchange with other healthcare organizations	65%
EMR	11%
Other (fax)	12%

Overall the survey responses demonstrated that the consent requirements are confusing, not only to the patients, but also to the providers charged with explaining the requirements and collecting the consent. It is clear that there is a burden to collecting consent and issues with work flow due to the complexities of the consent models across the State. The individuals responding to the survey provided notes and comments that were often specific to difficulties with form layouts, the forms being too long, and requirements to fill out forms for each RHIO. There is an overall desire to have more standardized forms and processes across the State for managing and collecting consent. There were also several requests for standardized, statewide training for both patients and providers to minimize the burden on practices to explain the complexities to patients during the registration process.

APPENDIX C: CONSENT ROUNDTABLE PARTICIPANTS

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