



To: NYeC Board of Directors

From: Art Levin, Chair, SHIN-NY Policy Committee

Date: January 23, 2017

Subject: Proposed Changes to SHIN-NY Consent Framework

This memo summarizes proposed changes to the consent framework governing the Statewide Health Information Network for New York (SHIN-NY) that the NYeC Policy Committee recommends for (i) adoption by the NYeC Board of Directors and (ii) submission to the New York State Department of Health (DOH) for further action, including changes to statutes, regulations, and the SHIN-NY policies and procedures, to the extent necessary.

I. Background on the Consent Review Process

These recommendations stem from a nearly year-long process to examine a central question: does the current SHIN-NY consent model serve as an obstacle to clinically important data exchange among SHIN-NY participants?

The process began with a survey of participants in Qualified Entities (QEs). The survey focused on obtaining responses from providers, but other types of entities, such as health insurers, were included in the survey. The survey was followed by interviews with a select number of participants; several of those interviewed were active participants in New York's Delivery System Reform Incentive Payment (DSRIP) program that aims to use health information exchange as a tool for improving care for Medicaid patients while reducing costs.

Based on the survey, follow-up interviews, a legal roundtable on consent rules and research into the consent model in New York and other states, NYeC produced a white paper on the impact of consent requirements on information exchange. The paper noted that fifty-five percent of survey respondents found that the consent requirements always, often, or sometimes prevented their organizations from obtaining patient information that could be used to deliver medical care. The white paper proposed four alternative models for further exploration: (1) a SHIN-NY wide consent model which would allow one consent form to apply to all participants in the state, (2) an opt-out model under which information could be shared without patient consent unless a patient opted out; (3) a flexible consent model under which different forms of consent could be shared; and (4) a blended model under which the consent requirements could differ depending on how information is being accessed.



Following the distribution of the white paper, NYeC conducted four focus groups to further understand issues related to consent. The four focus groups consisted of (1) health information exchanges in other states; (2) consumers and patient advocates; (3) QEs; and (4) privacy experts in New York State agencies.

A consent workgroup, consisting of a subset of members of the Policy Committee and other stakeholders, reviewed the white paper and focus group summaries and proposed a preliminary set of recommendations for changes to the consent model. Those recommendations were presented to the full Policy Committee on January 13. Based on feedback from the Policy Committee, those recommendations were refined, and are presented below.

II. Near Term Proposals

The following two proposals were reviewed by the Consent Workgroup and the Policy Committee, and a general consensus was reached at the Policy Committee to pursue these proposals. There were, however, a few members of these groups who had reservations about these proposals; some of their concerns are discussed in the attached “Recommendations for Consideration by the Consent Workgroup” document, which was presented to the Policy Committee and revised based on comments from Policy Committee members.

A. Alerts Without Consent

Under this proposal, hospitals could send an alert to certain providers, without patient consent, notifying them that the patient was admitted or discharged from an inpatient unit or emergency room. The recipient providers would have to have responsibility for providing treatment or care management to a patient and could include, for example, a primary care practitioner or a health home.

We recommend pursuing this proposal because many clinicians said during the consent review process that alerts are a highly valuable tool and that there are barriers under the current system to receiving such alerts. Moreover, alerts contain only a limited amount of patient information, and therefore sharing alerts does not raise the same level of privacy concerns as providing access to a patient’s entire record without consent.

B. Alternative Consent Forms

Currently, the SHIN-NY Policies and Procedures allow for the use of consent forms that meet strict requirements. QEs and participants can either use a form pre-approved by DOH or a form that contains all the elements required under the SHIN-NY policies.

Under this proposal, the consent form requirements would be liberalized and consent forms obtained in other contexts could be recognized as valid consent forms for access to the SHIN-NY. For example, the consent form that Medicaid beneficiaries agree to as part of the Medicaid application would be a recognized consent.



We recommend pursuing this proposal because it would result in the recognition of many additional consent forms, and therefore would allow greater sharing of information through the SHIN-NY, without changing the underlying requirement that patients grant consent to the sharing of their information in most circumstances.

III. Mid-to-Longer Term Proposals

In addition to the near term proposals, we recommend that the Board consider the following mid-to-longer term proposals for further consideration and development. These mid-to-longer term proposals were raised in the consent white paper and have been discussed with the Workgroup. Further in depth discussion by the Policy Committee as a whole including a broader group of stakeholder subject matter experts is proposed.

A. Opt-Out Model

Under an opt-out model, patient information could be exchanged through the SHIN-NY without patient consent unless a patient elected to opt-out of such information exchange. Such a model could significantly reduce burdens on QE participants and allow for the more free exchange of information, and it would further adoption and use of the SHIN-NY. It would also be a significant departure from the current model.

B. Data Segmentation

Under both state and federal law, certain forms of sensitive health information, such as records relating to substance abuse, abortions, and genetic tests, are subject to heightened consent requirements and therefore must be treated differently by QEs. Under this proposal, the state would develop guidance on how to segment such information to standardize the treatment of such information among QEs.

C. Centralized Consent Management System

Under this proposal, the state would support the development of a centralized consent management system, which would be a database that keeps track of every patient's consent choices. Such a system could allow patients to implement their consent choices online.

D. Patient and Participant Education

During the consent review process, respondents routinely stated that both patients and QE participants often lacked a good understanding of how information was shared electronically in New York State. Under this proposal, the state would invest in a robust patient and provider education campaign to improve patient understanding and train providers on the electronic exchange of information.



Background



Recommendations for Consideration by the Consent Workgroup

Not for Distribution

BACKGROUND

During the work of the SHIN-NY Policy Committee Consent Work Group over the last several months we have learned, among other things, that SHIN-NY stakeholders vary significantly in how they view the benefits and burdens of the current SHIN-NY consent policies and procedures and what changes in those policies, if any, they view as potentially of benefit.

In crafting our recommendations we have tried to remain sensitive to the diverse stakeholder opinions expressed in response to our survey as well as what we heard from the telephone interviews, legal roundtable discussion and the four focus groups that we convened.

Our charge was explicit: develop recommendations for consent policy changes that facilitate data sharing and at the same time respect patient privacy. We understand that the benefits of any such policy change should be measured by how well it serves the common goal of delivering high value, high quality healthcare to individuals and to populations in New York State.

LESSONS LEARNED

Our deliberations and research resulted in a number of lessons learned;

Maintaining the decade old, status quo of a unique SHIN-NY consent policy seems no longer defensible in the present environment of health care transformation efforts in New York State.



Much has changed in the decade since the SHIN-NY consent policies were first established and we now have a body of evidence that suggests a need for and a growing receptivity to change.

There is general agreement that a more “flexible” SHIN-NY consent policy could help make data sharing more robust and more valuable to stakeholders and users, and could relieve some of the consent burden experienced by some stakeholders.

At the same time there is agreement that any consent policy change must reflect continued respect for the privacy and confidentiality of individual patient information and be harmonized with current federal and state laws.

GUIDING PRINCIPLES

Any change in SHIN-NY consent policies should be incremental with near, mid and long term objectives and time lines.

Such an incremental approach would appear to be the most rational and most achievable and reflects:

(a) a recognition of the need to socialize any new policy among a diverse set of stakeholders, especially patients and consumers;

(b) a sensitivity to the time needed to implement and operationalize new approaches so as to ensure their successful integration into clinical work flow;

(c) an acknowledgement of the reality that more time is needed to mature technical capacities, the costs involved in implementation, and potential funding sources.



CRITERIA FOR NEAR TERM REVISIONS

We would suggest that “shovel readiness” is a reasonable “pass/fail” criteria for the adoption of any *near term* changes in consent policy. “Shovel readiness” would be determined by:

the degree of *legislative, legal and/or policy lift*, if any, necessary;

the degree of *operational complexity* or other technical considerations;

the degree of *stakeholder receptivity*, especially among patients and consumers, as a determinant of the *socialization* necessary; and

the perceived *value* of any consent policy changes in facilitating health care transformation efforts by the State.

PROPOSED RECOMMENDATIONS

The following sets forth proposals to reform the process for obtaining patient consent to exchange information through the SHIN-NY. These proposals are based on the analysis in the consent white paper and the feedback provided on the white paper in the four consent focus groups. These recommendations are intended to facilitate further discussion and determination of next steps by the New York State Department of Health.

Near Term Proposals

Alerts without Consent: Allow hospitals to notify primary care providers and other entities responsible for a patient’s care of a patient’s admission to or discharge from a hospital inpatient unit or emergency room without patient consent and with the ability for the patient to opt out.¹

¹ This exception would only apply to participants that have a treatment or care management relationship with a patient; participants that provide insurance coverage to a patient but have no responsibility for treatment or care management would not have access under this exception.



Rationale:

In discussions conducted as part of the research for the white paper, entities responsible for providing care management, such as managed care organizations (MCOs) and Performing Provider Systems (PPSs) operating under the Delivery System Reform Incentive Payment (DSRIP) program, emphasized that alerts were particularly useful in providing follow-up treatment/care coordination but expressed concern that consent requirements sometimes interfere with the ability to obtain such alerts.

In other discussions outside the white paper research process, it has become clear that alerts are highly valued by individual clinicians, especially those who have primary responsibility for a patient's care and thus must coordinate their care. It is also likely that patients stand to benefit from alerts since they are a prerequisite for meaningful care coordination.

Alerts contain a limited amount of patient information, and therefore sharing alerts does not raise the same level of privacy concerns as providing access to a patient's entire record without consent.

This recommendation aligns with the NY State Value Based Payment (VBP) Workgroup recommendations on patient confidentiality.

What Would be Required to Implement this Change?

The SHIN-NY Policies and Procedures and SHIN-NY regulation would need to be revised to allow this approach.

State law may also have to be amended to implement this approach. However, a modification to state law may not be required if: (a) the Department of Health (DOH) issued guidance stating this approach complied with the Public Health and Education Law; and (b) alerts were sent from hospitals subject to the Mental Hygiene Law only in cases where such alerts complied with Mental Hygiene Law § 33.13(d) (which would mean that such hospitals could send alerts to organizations such as health homes in some circumstances but could not send alerts to primary care physicians).²

² Mental Hygiene Law § 33.13(d) allows mental hospitals to share patient information without patient consent if (1) the information is being provided to a managed care organization, a behavioral health organization, a health home, or another entity authorized by the Office of Mental Health; and (2) the information is being used to arrange for or coordinate health care services for the patient. Thus, under this statute a mental hospital could send an alert to a health home in some circumstances, but the hospital could not send an alert to the patient's primary care physician absent consent.



Patients could opt out of the sharing of alerts by signing a form indicating that a particular participant should not be allowed to access the patient's information.

Some QEs may need to modify their software to implement this proposal.

Information about the alerts without consent and the opt-out option would need to be integrated into patient education.

Possible language for SHIN-NY Policies and Procedures:

"A Patient Care Alert may be provided to a Participant without Affirmative Consent provided that the recipient of such Patient Care Alert is a Participant that provides, or is responsible for providing, Treatment or Care Management to the patient. Such categories of Participants may include, but are not limited to, Practitioners, Accountable Care Organizations, Health Homes, Payer Organizations, PPS Lead Organizations, and PPS Partners who meet the requirements of the preceding sentence. If a patient or a patient's Personal Representative affirmatively denies consent to a Participant, then Patient Care Alerts shall not be transmitted to such Participant."

Concerns About Proposal Expressed by Workgroup/Policy Committee Members:

There are some privacy concerns related to the sharing of alerts. In some cases this exception would lead to a patient's alert being shared with an organization/entity without the patient's knowledge. In some cases the patient may not know the recipient of the alert (which may occur if a care management organization is charged with providing care to the patient and the patient has never previously interacted with such organization). In addition, while patients would have the right to opt-out of such a system, some patients are unlikely to exercise that right if they are unaware that their alerts are being shared. At least one member suggested that to make the opt-out option meaningful, and to promote patient knowledge of their care team, that patients be notified of all alerts that had been sent during an episode of care.

One Committee member noted that patients put the most trust in their treating providers, and that under the current model such providers are responsible for obtaining consent. A shift to an opt-out model, even if done only for alerts, could lead to less trust in the health care system.

If this proposal is implemented, some provider types such as primary care physicians may find a significant increase in the number of patient care alerts they receive, especially as they may have never actually met or treated some of the patients that are subject to those alerts. These providers would therefore need to develop a system for managing such alerts.



Alternative consent forms: No longer require a SHIN-NY consent form. Allow alternative consent forms that are not specific to the SHIN-NY to be used as the basis of exchanging information through the SHIN-NY, provided they adhere to state and federal law.

Rationale:

Other consents obtained from patients – such as the consent that individuals sign as part of the State Medicaid application, other health plan enrollment forms, or information sharing consent forms offered by individual providers – could satisfy SHIN-NY requirements. This approach would be particularly helpful to PPSs, which could obtain information about their attributed Medicaid beneficiaries through the SHIN-NY for population health purposes without an additional, SHIN-NY specific written consent.

What Would be Required to Implement this Change?

Participants would still be required to honor a written request by a patient to deny consent to a particular participant; such a denial would override an otherwise applicable consent form.³

Approach would require modifications to the SHIN-NY Policies and Procedures but there would not appear to be any need for statutory changes. These modifications will include specific language or guidance on form elements required to meet State approval for SHIN-NY access.

Any alternative consents related to health insurance enrollment would be non-durable, so that if a person disenrolled from such health insurance their consent would no longer be valid. This would therefore require insurers to share information on consent with QEs continuously. In the case of Medicaid beneficiaries, a system would need to be developed under which DOH could transmit to QEs information on individuals who have consented to information sharing as part of the enrollment

³ In regards to Medicaid beneficiaries, the state could take the position that any Medicaid beneficiary that opted out of information sharing under DSRIP does not like their information being shared and therefore alternative consent forms should not be valid for such patients. However, matching the names of individuals on the DSRIP opt-out list with patients in the QE may pose implementation challenges.



process; the information could be transmitted to each QE directly or to a centralized entity (see centralized consent management system proposal).

The required language or form elements could be incorporated into existing forms for enrollment or information sharing used by various health plans and providers, and would not be limited to the Medicaid enrollment form.

DOH would need to review alternative consent forms and inform QEs whether a form meets the minimum standards. If a form is not as broad as the current SHIN-NY consent form (i.e., it does not allow for exchanges for all the purposes set out in the current standard form), DOH and the QEs will need to determine whether such a form can be used as the basis for information exchange.

Participants may need to be trained on the alternative consent form rules, and QEs may need to audit such participants to ensure that they are only relying on alternative forms approved by DOH.

This approach would not permit sharing of Part 2 data because of the more stringent federal requirements regarding Part 2 consent forms. A separate consent form would be used for Part 2 data.

Some QEs may need to modify their software to implement this proposal.

<i>Possible language for SHIN-NY Policies and Procedures:</i>
"Affirmative Consent to access information via the SHIN-NY governed by a QE for Level 1 Uses shall be obtained using a paper or electronic consent form which shall include the following information:
(a) The name(s) or description of both the source(s) and potential recipient(s) of the patient's information. A general description, such as "information may be exchanged among providers that provide me with treatment," shall meet this requirement;
(b) The intended uses of the information by the recipient(s) of such information. A general description, such as "for treatment, care management or quality improvement," shall meet this requirement;



(c) If the information which may be exchanged may include HIV, mental health, alcohol and substance abuse, reproductive health, sexually-transmitted disease, and genetic testing information, a notification to the patient that such information, as applicable, may be transmitted to the recipient; and

(d) The signature of the patient or the patient’s Personal Representative. If the consent language required under subsections (a), (b), and (c) above is incorporated into another document such as a health insurance enrollment form, the signature need not appear on the same page as the language required under subsections (a), (b), and (c) above.”

Concerns About Proposal Expressed by Workgroup/Policy Committee Members:

The alternative consent forms may not align with the current SHIN-NY consent forms. For example, if the consent form relates to a health insurance enrollment it is possible that such form could apply only to the insurer’s network providers (not to all providers in a QE) or may allow exchanges that only relate to covered benefits (and not allow for information exchanges that relate to non-covered benefits). Given this, DOH may need to develop an interpretation of each alternative consent form and inform QEs about any relevant limitations on information exchange.

The implementation challenges, including revising QE software to allow for alternative consent forms, may be significant. The benefits therefore may not be worth the costs, particularly for QEs that have implemented community-wide consent and therefore have less to gain from this proposal.

There are some privacy concerns with the proposal, since a consent tied to health insurance enrollment could be viewed as a contract of adhesion. This could be addressed by making the QE or SHIN-NY consent a separate decision on the enrollment form, and allowing the member to either grant or deny consent (although this option would require Medicaid and health insurers to redesign their enrollment forms).

The non-durability of consent may interfere with care. For example, a provider may access a Medicaid beneficiary’s information through the SHIN-NY in accordance with the consent granted under the Medicaid enrollment form. If the patient leaves Medicaid but continues to see the provider, the provider would no longer have access to the patient’s information in the SHIN-NY; the patient would need to sign another consent form to allow the provider to retain such access.

Attention still has to be paid to patient education about the SHIN-NY regarding the use of their data, so the proposal should at least reference the availability of more information about the SHIN-NY.



III. *Access Following Referral or Appointment:* The Workgroup originally proposed to allow Participants to view a patient’s information in the SHIN-NY without patient consent if the patient has scheduled an appointment with such Participant or has been referred to such Participant for treatment or care management. However, this proposal has been removed from consideration out of concern from the workgroup that the use cases that apply to this exception (other than use cases already covered under the one-to-one exception) have not been sufficiently defined.

Mid to Longer Term Proposals⁴

Data segmentation: State develops guidance that standardizes how QEs should identify and segment Part 2 information or other highly sensitive information (e.g., abortion services and genetic test results).

Rationale:

Since Part 2 and possibly other sensitive information is subject to more stringent rules than other types of data, it is critical that QEs develop the capacity to identify and segregate such data. However, QEs have different interpretations of federal rules and different means of identifying sensitive data. The different approaches have interfered with information exchanges between different QEs. DOH efforts could focus on harmonizing these different approaches.

What Would be Required to Implement this Proposal?

State guidance could standardize QE policies and technical solutions and remove the obstacles caused by differing interpretations and standards related to sharing of Part 2 information.

Some QEs may need to modify their software to implement this proposal.

⁴ While the near term proposals were discussed at the January 13, 2017 Policy Committee meeting, the mid to longer term proposals have not yet been subject to in depth discussions by the Policy Committee and only were discussed in the context of the white paper prior to its publication.



Centralized Consent management system: State supports the development of a statewide consent management system.

Rationale:

Such a system would support the change in requirements related to the need for a specific SHIN-NY form of consent where other existing State approved forms could be used to register a patient's consent status. It would make it easier for patients to provide consent to care coordinators who lack patient contact, a key concern identified in the white paper.

What Would be Required to Implement this Proposal?

A priority would be determining whether it is feasible for EHRs to incorporate information from the statewide system; if EHRs are unable to do this then the system may be of little use.

Operationalizing centralized consent may be administratively difficult and would require adoption of many of the same practices that are used under a community-wide consent model. Although two QEs (HEALTHeLINK and Healthix) currently allow community-wide consent, six QEs have determined that the complications of implementing community-wide consent outweigh its benefits in their regions. Challenges related to authentication of individuals and matching of patient records may be critical to successfully implementing this model.

A centralized consent management system may help implement the alternative consent form, since DOH may be more willing to share Medicaid consent information with one entity (which would then share the beneficiary's consent decisions with the QEs) instead of all of the QEs. This may hold true for other forms of consent approved for use in the SHIN-NY.

Patient education: State develops a roadmap for development of a patient and participant education campaign explaining how information is shared electronically.



Rationale:

The consumer/patient advocate panel was critical of providers' knowledge of information exchange and said providers often did not do enough to explain how their patients' information was being shared. This concern echoed a finding of the consent survey, which found that participants did not emphasize patient discussion/education. If patients and SHIN-NY participants had a better understanding of information exchange, consent would be more likely to be informed.

Longer term outcomes of a consumer and participant education campaign could be the development and implementation of a patient centric system that allows patients to manage their consent via existing patient portals.

Opt-out: State explores the feasibility of establishing an opt-out system, under which patient information could be exchanged without patient consent so long as exchange complies with HIPAA and the patient is given the right to opt-out.

Rationale:

In the white paper survey and follow-up responses, many participants recommended a switch to an opt-out system as a means of fulfilling the promise of electronic sharing of information. They noted that the process to obtain patient consent is cumbersome, and that information exchange will always be limited so long as participants must have patient consent, or show that a consent exception exists, in order to exchange patient information.

An opt-out system could encourage greater use of the SHIN-NY and therefore make the QEs more valuable to participants throughout the state.

Other states have successfully implemented opt-out systems.

What Would be Required to Implement this Proposal?

Steps would need to be taken to help protect patient privacy under an opt-out system. Importantly, patients would need to be made aware of the SHIN-NY and their right to opt-out of information exchange, and therefore patient education is a critical piece of such a system (see patient education proposal).



A shift to opt-out would be a fundamental alteration of the New York consent landscape and would require further discussion with stakeholders to generate broader buy-in.

Many state laws require patient consent, and those laws would need to be revised. The SHIN-NY regulations and SHIN-NY policies would also need to be amended.

A system for tracking opt-outs would need to be developed. Ideally, patients would have the ability to opt-out online, but allowing patients to do so would be a technological challenge (see centralized consent management proposal).

An opt-out system would not comply with 42 C.F.R. Part 2, and therefore Part 2 data would need to be segmented from other data in order to implement this proposal, as discussed in the data segmentation proposal (although the revised Part 2 rule may require segmentation anyway). Part 2 data would need to be exchanged under a separate opt-in process.