Notice and Comment: Changes to the SHIN-NY Consent Rules

Introduction

The New York State Department of Health (DOH) is seeking comment on proposals to modify the consent framework governing the Statewide Health Information Network for New York (SHIN-NY). These proposals stem from an analysis of the SHIN-NY consent rules that DOH, the New York eHealth Collaborative, and other stakeholders undertook in 2016 and early 2017.

For two of the proposals, regarding patient alerts and alternative consent forms, DOH is proposing language to modify the Privacy and Security Policies and Procedures for Qualified Entities and their Participants in New York State (the Policies). DOH oversees the Policies, which set forth the privacy rules that govern exchanges through QEs. Subject to conformance with state law and any revision of the SHIN-NY regulations that DOH may deem necessary, DOH will seek to modify the Policies after the end of the notice and comment period, taking into account the comments its receives.

The remaining proposals cannot be implemented in a short-term timeframe. DOH is not proposing specific changes to the Policies for these proposals at this time, as several of these proposals may require funding adjustments or a change in state law in order to be implemented. DOH is seeking comments on these proposals as well in order to better understand the receptivity of stakeholders to these proposals, the costs and benefits of such changes, and any barriers to implementation.

Comments should be provided on the short-term proposals by April 27, 2017 and on the mid-to-long term proposals by May 12, 2017. Comments should be submitted to publiccomments@nyehealth.org.

Short-Term Proposals

Patients Alerts

Rationale for Revision

In undertaking a review of the SHIN-NY consent requirements, DOH heard from many providers and health plans about the importance of receiving alerts about their patients. Alerts contain information about a development in the patient's medical care, such as an admission to an emergency room or the discharge from a hospital. From the perspective of a primary care provider or other individual or organization charged with managing a patient's care, alerts can be critical information, since the alerts inform that individual or organization that the patient may be in need of follow-up care. Moreover, alerts are timely: they are sent at the time when the patient is in need of additional care, not weeks after an episode when a medical intervention is less likely to have a positive impact on patient care.

However, under the Policies alerts typically will require written affirmative consent in order to be exchanged. In some cases, the person or organization seeking the alert may have already obtained such consent: if a primary care provider works closely with a patient, he or she may have already discussed the SHIN-NY with a patient and obtained that patient's consent. But in other situations, written consent is more difficult to obtain. For example, a physician's office may contract with an outside organization to provide care management, and while the physician's office may have the patient's written consent, the outside organization may not.

In addition, sharing of alerts do not raise the same privacy concerns as other types of medical information. Alerts have basic information such as the patient's date and location of care. It does not include detailed information on diagnoses on treatment, and therefore typically does not convey any "sensitive" health information. The Participant receiving the alert is not granted full access to the patient's medical record, and is not allowed to search the SHIN-NY for more information on the patient unless the Participant obtains written consent. Moreover, this provision will prohibit alerts from being sent from substance use disorder facilities subject to 42 C.F.R Part 2 and mental health facilities (unless the requirements of Mental Hygiene Law § 33.13(d) are met).[1]

For these reasons, DOH has concluded that there are substantial benefits in allowing Participants to have greater access to patient alerts. We therefore are proposing to revise the Policies to allow alerts to be sent in some circumstances without written consent of the patient.

Language Changes to the Policies

We propose to revise the Policies as follows:

"1.10 Receipt of Patient Care Alerts.

1.10.1 ~~A Participant may receive Patient Care Alerts from a QE with respect to any patient from whom the Participant has obtained Affirmative Consent.~~ 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. Patient Care Alerts may be sent from facilities subject to the New York Mental Hygiene Law without Affirmative Consent only if such alerts comply with Mental Hygiene Law § 33.13(d). Patient Care Alerts may not be sent from any facilities subject to 42 C.F.R. Part 2 without Affirmative Consent.

[1] Mental Hygiene Law § 33.13(d) would allow alerts to be shared with Health Homes and other categories of providers in some circumstances but would not allow sharing of information with primary care providers.

1.10.2 Patient Care Alerts containing Protected Health Information shall be sent in an encrypted form that complies with U.S. Health and Human Services Department Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals."

Alternative Consent Forms

Rationale for Revision

Under the current version of the Policies, if a Participant seeks to access information in the SHIN-NY for purposes of treatment, quality improvement, care management, or insurance coverage reviews, and no exception to the requirement to obtain written patient consent from the patient applies, then the Participant has two options for consent forms. The Participant may provide the patient with a "Level 1 Consent," which is a standard consent form developed by DOH. Alternatively, the Participant may provide the patient with an alternative consent form that is "substantially similar" to the Level 1 Consent form, meets ten separate requirements, and has been approved by DOH.

Practically, the Policies mean that alternative consent forms are largely the same as the official DOH Level 1 Consent form, with minor changes. The strict requirements mean that other consent forms that are widely in use cannot be used to exchange information through the SHIN-NY. For example, as part of their enrollment application New York State Medicaid beneficiaries agree to the release of their health information to their health plan and providers for purposes of treatment, payment, or health care operations, but because that form does not meet every one of the ten requirements for alternative consent forms it cannot not be used as a basis for exchanging information through the SHIN-NY.

DOH has concluded that the strict alternative consent form rules are no longer justified. These requirements mean that patients who have granted written consent to the exchange of their health information often still cannot have their information shared for purposes of providing them with care. The requirements are not in the best interest of patients, nor do they serve other policy goals.

We are therefore proposing to modify the Policies to reduce the number of requirements for alternative consent forms. Under the proposal, alternative consent forms still must meet certain basic standards: there must be a general description of the information being exchanged, the source of the information, and the potential recipients of the information, for example. But more detailed requirements – such as a requirement that there be a certification that only those engaged in Level 1 information may access the information – would be eliminated. We believe that by streamlining these requirements, different categories of consent forms can be used as the basis of sharing information in the SHIN-NY.

We are also proposing to modify the Policies to allow QEs to approve alternative consent forms as well. Organizations can continue to turn to DOH for requests to approve such forms, but by

allowing QEs to approve such forms as well DOH believes that the use of alternative consent forms will be further encouraged.

We note that the proposed changes in the Policies are not intended to change the substantive requirements for alternative consent forms used for Level 2 Uses, as defined by the Policies. We are proposing to modify the description of the Level 2 consent form requirements only because the Level 2 consent form requirements refer to the Level 1 requirements, and since we are proposing to modify the Level 1 requirements a conforming change must be made to the Level 2 language. However, the change in the Policies would allow QEs to approve alternative Level 2 consent forms as well.

Language Changes to the Policies

We propose to revise the Policies as follows:

Definitions:

"Affirmative Consent means the consent of a patient obtained through the patient's execution of (i) a Level 1 Consent; (ii) a Level 2 Consent; (iii) a consent mechanism approved by NYSDOH or a QE as an alternative to a Level 1 Consent or a Level 2 Consent under Section 1.3; or (iv) a consent that may be relied upon under the Patient Consent Transition Rules set forth in Section 1.9.2."

"1.3 Form of Patient Consent. Except as otherwise permitted by the Patient Consent Transition Rules set forth at Section 1.9, consents shall be obtained through an Approved Consent. NYSDOH or a QE may approve an alternative to a Level 1 Consent or a Level 2 Consent if the alternative consent form includes the information specified in this section~~A QE may request approval to use a consent other than a Level 1 Consent or Level 2 Consent if it obtains approval from NYSDOH. Such approval will not be granted unless the alternative consent is substantially similar to the Level 1 Consent or Level 2 Consent, as applicable, and achieves the same basic purposes as such consents, as set forth in these Policies and Procedures~~.

1.3.1 Level 1 Uses. Affirmative Consent to access information via the SHIN-NY governed by a QE for Level 1 Uses shall be obtained using a Level 1 Consent or an alternative approved by NYSDOH or a QE under Section 1.3, which shall include the following information:

a. The information to which the patient is granting the Participant access, including specific reference to HIV, mental health, alcohol and substance abuse, reproductive health, sexually-transmitted disease, and genetic testing information, if such categories of information may be transmitted to the recipient;

b. The intended uses to which the information will be put by the Participant. A general description, such as "for treatment, care management or quality improvement," shall meet this requirement;

c. ~~The relationship between the Participant and the patient whose information will be accessed~~ 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; and

~~d. A list of or reference to all Data Suppliers at the time of the patient's consent, as well as an acknowledgement that Data Suppliers may change over time and instructions for patients to access an up-to-date list of Data Suppliers through a QE website or other means; the consent form shall also identify whether the QE is party to data sharing agreements with other QEs and, if so, provide instructions for patients to access an up-to-date list of Data Suppliers from a QE website or by other means; 12~~

~~e. Certification that only those engaged in Level 1 Uses may access the patient's information;~~

~~f. Acknowledgement of the patient's right to revoke consent and assurance that treatment will not be affected as a result;~~

~~g. Whether and to what extent information is subject to re-disclosure;~~

~~h. The time period during which the consent is to be effective;~~

~~i~~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.~~;~~ ~~and,~~

~~j. The date of execution of the consent.~~

1.3.2 Level 2 Uses. Consent to access information via the SHIN-NY governed by a QE for the purposes of Level 2 Uses shall be obtained using a Level 2 Consent or an alternative consent approved by NYSDOH or a QE under Section 1.3, which shall include (i) the information required of a Level 1 Consent pursuant to Section 1.3.1 and (ii) the following:

a. The specific purpose for which information is being accessed;

b. Whether the QE and/or its Participants will benefit financially as a result of the use/disclosure of the information to which the patient granting access;

c. The date or event upon which the patient's consent expires;

d. Acknowledgement that payers may not condition health plan enrollment and receipt of benefits on a patient's decision to grant or withhold consent.

e. A list of or reference to all Data Suppliers at the time of the patient's consent, as well as an acknowledgement that Data Suppliers may change over time and instructions for patients to access an up-to-date list of Data Suppliers through a QE website or other means; the consent form shall also identify whether the QE is party to data sharing agreements with other QEs and, if so, provide instructions for patients to access an up-to-date list of Data Suppliers from a QE website or by other means;

f. Acknowledgement of the patient's right to revoke consent and assurance that treatment will not be affected as a result;

g. Whether and to what extent information is subject to re-disclosure;

h. The date of execution of the consent."

Mid-to-Long Term Proposals

Data Segmentation

Under this proposal, DOH would aim to standardize how QEs identify and segment information subject to 42 C.F.R. Part 2 or other highly sensitive information, such as information related to abortion services and genetic test results.

The purpose of this proposal is to promote information exchange of information between QEs. Since Part 2 and 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. We aim to harmonize these different approaches.

Centralized Consent Management System

Under this proposal, the State would support the development of a statewide consent management system.

The purpose of this proposal is to improve the ability of QEs to share information on their patients' consent choices. With millions of patients signing a SHIN-NY consent, QEs using different consent models (community-wide consent vs single-consent model), and the possibility that different types of consent forms may soon become more common, it is a challenge to keep track of who has signed a consent, and what exactly that person has consented to. A centralized, statewide consent management system may help QEs ensure that they are following the consent choices that their patients have made.

There may be many operational challenges to such a proposal, such as challenges related to authentication of individuals and matching of patient records. DOH welcomes comments on these issues.

Patient Education

Under this proposal, the State would launch a patient and participant education campaign explaining how information is shared electronically.

The purpose of this proposal is to improve both patient and participant understanding of the SHIN-NY so that patients can make informed choices about the sharing of their health information. In our analysis of the current consent model, we repeatedly heard concerns about patients and participants lacking knowledge on how information is shared electronically, and we are seeking comment as to whether a patient education campaign will help improve such understanding.

Opt-Out Model

Under this proposal, the State would switch to 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 of such exchange.

This proposal would represent a significant shift from the current consent model, which requires patient consent for the exchange of information subject to limited exceptions, and implementing this proposal would require a change to State law. The goal of the proposal is to eliminate barriers to the sharing of patient information and make it easier for participants who are providing care to a patient to access a patient's information. The proposal also has important privacy implications, and we seek comments on both the costs and benefits of shifting to such a model.