

New York eHealth Collaborative Policy Committee Meeting
May 12, 2015
9:00 a.m. – 11:00 a.m.
Meeting Notes

A meeting of the NYeC Policy Committee was held on May 12, 2015. Present either in person or via telephone were:

Art Levin, Center for Medical Consumers, Co-Chair Policy Committee
David P. Martin, Consumer Health Care Advocate
Dr. Thomas Mahoney, Finger Lakes Health Systems Agency
Dr. Glenn Martin, Queens Health Network
Nance Shatzkin, Bronx RHIO
Ronnie Pawelko, JD, Family Planning Advocates of NYS
Steve Allen, HealthLink
James Kirkwood, NYS DOH
Jonathan Karmel, NYS DOH
Paul Schaeffer, New York City Department of Health and Mental Hygiene
Linda Adamson, New York City Department of Health and Mental Hygiene
Dr. David Cohen, Maimonides Medical Center
Ted Kremer, Rochester RHIO
Tom Check, Healthix RHIO
John Rodat, Public Signals, LLC
Gus Birkhead, NY State DOH Office of Public Health.
Corinne Carey, NYCLU
Dr. Amanda Parsons, Montefiore
Geraldine Johnson, NYS DOH
Cindy Sutliff, NYeC
Inez Sieben, NYeC
Vinay Chopra, NYeC
Elizabeth Amato, NYeC
Bob Belfort, Manatt
Alex Dworkowitz, Manatt

The meeting was called to order by Mr. Levin at 9:00 a.m.

I. Welcome and Meeting Objectives

Mr. Levin welcomed everyone to the meeting and introduced Mr. Karmel and Mr. Kirkwood from the New York State Department of Health (“NYS DOH”) to discuss the updated draft SHIN-NY regulation.

II. NYS DOH Update on Draft SHIN-NY Regulation

Mr. Kirkwood explained that NYS DOH was not issuing a revised draft of the previously issued regulation. Instead, it would be considered a new regulation for purposes of the state’s

Administrative Procedures Act. Mr. Kirkwood said that NYS DOH hoped to have the proposed regulations in the state register by August.

III. Comments on Draft SHIN-NY Regulation

Ms. Sutliff explained that the Policy Committee had several comments on the draft regulation relating to community-wide consent, patient rights, and the form of consent. In addition, the minor consent Tiger Team had discussed the minor consent provision in the draft regulation and was seeking a change in the regulations to make it clear that the Let-the-Data-Flow model was permitted. Ms. Sutliff introduced Mr. Belfort to discuss these issues further. (see charted issues and follow up actions from previous discussions)

Mr. Belfort said the issues of a need for a minor consent form and the reference in the regulations to practitioners being subject to the Education Law were discussed in the previous meeting.

Consent form

Mr. Karmel said that NYS DOH was trying to move away from a system of regional organizations and more toward a statewide system, and therefore it is important for all Qualified Entities (“QEs”) to work together. Having uniformity among consent forms would be helpful. However, guidance has already been issued in terms of consent forms, and the forms that QEs are using are substantially similar. Ms. Shatzkin asked if that means that DOH would require a standardized consent form. Mr. Karmel said that NYS DOH would not require QEs to use a standardized consent form.

Ms. Shatzkin said QEs currently need to get approval to make changes to the consent form. Mr. Karmel said that QEs must follow the rules under the grant contracts. Ms. Shatzkin said that her QE follows the SHIN-NY Policies and Procedures (the “Policies”). Mr. Karmel responded that the grant contracts incorporate the Policies. Ms. Shatzkin said that since the QEs need to follow the Policies, they still must have changes to the consent form reviewed by the policy director at NYeC or someone from DOH.

Ms. Carey questioned why NYS DOH did not want to adopt a standardized consent form given the agency’s position in favor of uniformity. Mr. Karmel said that the QEs all use forms that are substantially similar to the required consent, and that NYS DOH does not want to be in the business of approving consent forms. Ms. Carey said her concern is that the consent forms being used are not substantially the same.

Ms. Sutliff said she expects to see something on NYS DOH’s website that provides guidance on consent forms and has a copy of a standard form.

Section 6530 of the Education Law

Mr. Belfort asked about the meaning of the reference to Section 6530 of the Education Law in the draft regulations. Mr. Karmel said that the intent was to capture the idea that providers could

engage in a one-to-one exchange, but he would be willing to revise the language. Mr. Belfort said that the Policy Committee could work on proposing draft language to capture the idea of a one-to-one exchange. Mr. Karmel said that this is possible, but that the one-to-one exchange concept is hard to define. Mr. Check noted that not only providers could engage in one-to-one exchanges; all Participants can do so. These comments will be included in a draft comment letter from the Policy Committee to the SDOH as part of this informal comment period.

Community-Wide Consent

Mr. Belfort said there is a lot of interest in the community-wide consent model, especially in regards to the Delivery System Reform Incentive Payment (“DSRIP”) Program. Mr. Belfort said he wanted to make sure that NYS DOH has provided guidance that this model is permissible under state confidentiality laws, and that QEs would not be required to list all Participants on the consent form. Mr. Belfort said the regulation did not provide any guidance as to what type of notice was required. Mr. Belfort said the regulation could be interpreted to allow a QE to simply list new Participants on the website; alternatively, it could require QEs to send letters to patients across the state.

Mr. Karmel said that Article 27 of the Public Health Law, which protects HIV information, was modeled on the federal substance abuse law, and that FAQs on the federal substance abuse law show that you cannot use a global consent form. Under the mental hygiene law, there must be a demonstrable need for the information. If you have a global consent, that should be sufficient under the mental hygiene law, Mr. Karmel said. Mr. Karmel added that 99.9% of the time it is appropriate for a provider treating a patient with HIV to know the HIV status of that patient.

Mr. Karmel said that the names of all Participants should be listed on the form. Mr. Allen said that for five years, his QE has used a multi-provider consent form and has listed the Participants on a website, not on the form itself. Mr. Allen said they do not do this for Part 2 substance abuse data. Mr. Karmel said that what the QE was doing was in compliance with state law.

Ms. Shatzkin said that Mr. Allen’s model only applied the community-wide consent to current Participants, not for future Participants. Ms. Shatzkin asked if Mr. Karmel subscribed to the current Participant/future Participant distinction in the regulations. Mr. Karmel said that the regulation will be New York State law. Mr. Karmel said it was unclear whether the global consent currently complies with state law, but if they issue the draft regulation, it will be clear that such global consent does comply with state law.

Ms. Sutliff noted that there is still the issue of the community-wide consent complying with the federal substance abuse rules. Dr. Cohen said that the Substance Abuse and Mental Health Services Administration (“SAMHSA”) was thinking about an adjustment to federal law in regards to this issue, and such adjustment might happen this summer.

Mr. Belfort summarized NYS DOH’s position: NYS DOH was saying that the regulation is authorizing the community-wide consent model under state law but that Part 2 data would continue to have to be carved out. Mr. Karmel said that he was open to suggestions on the notice

pieces. Mr. Belfort said that the Policy Committee could work on suggestions for possible inclusion in the comment letter.

Patients' Rights

Mr. Belfort said the draft regulation does not reference a patient's right to access his or her own records, and that it does not reference the right to obtain an accounting of how information has been disclosed. Mr. Belfort said that referencing those rights in the regulation would be helpful.

Mr. Karmel said that NYS DOH is going to add patients' rights back into the regulation, and that it will include a right to access patient information and the right to get an accounting.

Mr. Levin asked whether that meant that patients would have a right to access the data in electronic format and see what the Participants saw. Mr. Karmel said to literally see the same thing, the patient would need an Electronic Health Record ("EHR") system. Ms. Sutliff said the Policies allow for electronic access where possible, but at the very least require the provision of a paper copy, and that they should consider leaving this in the Policies for now.

IV. Patient Access Survey

Mr. Belfort said the current version of the Policies go beyond what HIPAA requires from an accounting standpoint. HIPAA only requires that information be given about the institution that accessed the patient's information, not the name of the actual individual.

Ms. Sutliff said that NYeC had received five responses to the survey that was sent to all QEs and that asked about current practices related to requests for accounting of disclosures from patients. The survey results show that QEs are willing to provide some information, but they vary in the level of detail. Some QEs do not provide the name of the individual who accessed the data and leave it to the Participant to provide that information. The general consensus from the QEs is that they would prefer not to provide the name of the individual who accessed the record, and that they should instead leave it to the Participant to provide that information.

Mr. Allen said that the QEs don't feel they have the right to provide individual-level information—that this is an issue between the patient and the Participant.

Mr. Levin said the patient was in the best position to police the flow of protected health information. Dr. Martin said that if a hospital has 10,000 voluntary staffers who work there, then a patient will have little idea who accessed their information. Mr. Allen said a patient was much better off calling the hospital to determine if a person wrongfully accessed his or her data, since the QE can only provide information on data accessed through the QE and not data accessed through the hospital's own system.

Mr. Check said that his QE asks the Participant to provide the patient with information on the individual who accessed the patient's data because the QE has no way of authenticating the user. The QE does not have contact with the patients, but the hospitals do. Mr. Belfort said that the

institution may be in a better position, but there is no obligation on the institution to provide the information.

Mr. Martin said that requiring the patient to pursue the information from the institution could be unduly burdensome on the patient, particularly if the patient is ill or mobility impaired. He suggested that if the policy is changed, patients should be told that there is no requirement to provide an individual level accounting before the patient signs the consent form. Dr. Glenn Martin said that they could have a system under which an email was sent to the patient every time a person accessed that patient's chart.

Mr. Mahoney asked what the responsibility of an institution is to provide this information. Mr. Allen said that QEs can require an audit of a Participant. If the QE gets a call of a concern, the QE can require the Participant's privacy officer to attest that the access was permissible.

Ms. Sutliff recommended that the Policies be revised to remove the requirement that a QE specify the individuals who accessed the patient's record, until the patient portal allows patients to access this information.

Mr. Levin asked if the regulation addressed this issue. Mr. Karmel said the prior version of the regulation had addressed this. Ms. Sutliff said she does not think the regulation should address this issue, and that they would work on a proposal to amend the Policies.

V. Terminating Authorized User Access Under the Policies (Section 4.8.2)

Mr. Dworkowitz explained that the current version of the Policies do not have any provision addressing whether an authorized user's access to the SHIN-NY needs to be terminated if that user's role changes so that access to the SHIN-NY is no longer appropriate. Mr. Dworkowitz said that Mr. Allen had made a suggestion for such a change, and that a proposed revision had been drafted based on Mr. Allen's suggestion. However, at a previous meeting several members of the Policy Committee expressed concern about the draft proposal's requirement that providers implement such a change within one day of the change in roles. Mr. Dworkowitz said that the draft language had been revised to require that access be restricted "as promptly as reasonably practicable."

Ms. Shatzkin asked if QEs still were required to terminate access within one day after learning from a Participant that a role-change had occurred. Mr. Dworkowitz said that QEs still faced the one-day requirement.

VI. Additional Policy Discussion

Break the Glass

Mr. Allen noted that the Policies section on "Breaking the Glass" when treating a patient in an emergency requires the Participant to notify the patient if a Break the Glass incident occurred

and inform the patient how an audit log can be requested in accordance with Section 6.1.1(h) of the Policies. Mr. Allen said he thought the reference to Section 6.1.1(h) was incorrect.

Ms. Sutliff said there had been some confusion about when the notice had to be provided. The notice needs to be provided within 10 days discharge from the emergency room. She said a standard notice should be included in the discharge papers.

Mr. Allen said that the notice should identify the facility and date and how to contact the facility. He said clarity is needed as to what the notice should contain. Ms. Sutliff said this type of thing need not go into the Policies, and it could perhaps be an issue for the implementation subcommittee to address. Mr. Allen said that this was fine, but that the reference to 6.1.1(h) still seemed incorrect. Ms. Shatzkin said that they would check the reference.

Level 1 Use for Family History

Mr. Allen said in some cases, learning the family history of a patient is very relevant. For example, a genetics group wants information on family members of patients, but they do not have a treating relationship with those family members. Mr. Allen said a Level 1 consent form cannot be used to obtain information from the family members in this situation because they are not being treated.

Dr. Glenn Martin said that in most situations, the genetics counselor asks the patient to collect information about the family members and does not try to collect the information on his or her own. Ms. Shatzkin said that might be the case, but that the expansion of technology through the SHIN-NY creates a new potential means for the geneticist to access information.

Mr. Karmel said that a Level 1 consent form would not be adequate because care was not being provided to a family member, although it is possible that this could be a one-to-one exchange. Mr. Belfort said that if the geneticist wanted to search the entire SHIN-NY for medical records that this would not be a one-to-one exchange, but this could qualify as a Level 2 exchange. Ms. Sutliff said that this was an interesting thought and that something should be drafted on this issue.

VII. Update on Let the Data Flow for Exchange of Minor Health Information

Ms. Sutliff said that the Tiger Team does have a recommendation for revising the draft SHIN-NY regulations in regards to the sharing of minor consent information. She said that NYS DOH has been discussing the Tiger Team's recommendation, and that the issue will be discussed at the Policy Committee's next meeting and included in the comment letter to the SDOH.

VIII. Upcoming Meeting

Ms. Sutliff said that the next Policy Committee meeting will take place on June 9, and it will be a face to face meeting. She said that the Policy Committee suggestions on the draft regulation as discussed will be fine-tuned and submitted to SDOH prior to its release for public comment

sometime in August. Ms. Sutliff also said that an update to the patient portal can be presented at the meeting.

IX. Next Steps

- NYeC will draft recommended changes to the draft SHIN-NY regulation regarding one-to-one exchanges and the notice requirement for community-wide consent to be forwarded as part of the informal comments to SDOH along with the other issues as discussed.
- NYeC will draft a recommended change to the Policies to end the requirement that QEs provide a list of authorized users who accessed a patient's log.
- NYeC will also review the break the glass section of the Policies to see if the reference to Section 6.1.1(h) is correct and will examine the use of a Level 2 consent form to obtain genetics information for family members of a patient.

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