

**New York eHealth Collaborative
SHIN-NY Policy Committee Meeting
October 13, 2015
9:00 a.m. – 11:00 a.m.
Meeting Notes**

A meeting of the SHIN-NY Policy Committee was held on October 13, 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
Nance Shatzkin, Bronx RHIO
Steve Allen, HealthLink
James Kirkwood, NYS DOH
Jonathan Karmel, NYS DOH
Christie Allen, NYS DOH
Geraldine Johnson, NYS DOH
Victoria Choi, NYS DOH
Paul Schaeffer, New York City Department of Health and Mental Hygiene
Dr. David Cohen, Maimonides Medical Center
Ted Kremer, Rochester RHIO
Dr. Amanda Parsons, Montefiore
Dr. John-Paul Mead, Cayuga Medical Associates, P.C.
Dr. Glenn Martin, Queens Health Network
Tom Check, Healthix RHIO
Colleen Mooney, NYSTEC
Shannon Kinnear, NYSTEC
Cindy Sutliff, NYeC
Inez Sieben, NYeC
Bob Belfort, Manatt
Alex Dworkowitz, Manatt
Amy Warner, Rochester RHIO
Zeynep Sumer-King, GNYHA

The meeting was called to order by Mr. Levin at 9:00 a.m. Ms. Sutliff noted that Mr. Check had some revisions to the meeting minutes, and that she would resend the minutes to the group. Mr. Levin encouraged Committee members to submit any corrections or comments to the meeting notes that they may have.

I. NYS DOH Update

Mr. Levin introduced Mr. Kirkwood from the New York State Department of Health (“NYS DOH”) to discuss the draft SHIN-NY regulation. Mr. Kirkwood said the regulations had made it past NYS DOH and the budget office, and now they were with the governor’s counsel’s office.

There is a public health council meeting in early December, and NYS DOH was targeting to release the regulations for public comment after that date.

Mr. Kirkwood said there have not been substantial changes to the regulations as they have gone through the process. There was a comment at a NYeC board meeting that hospitals should be required to connect within one year after the Regulation is codified, so there was a change to that effect. There was also a change to ensure that the New York City Department of Health and Mental Hygiene can use the SHIN-NY for public health investigation.

In response to a question from Ms. Sutliff, Mr. Kirkwood confirmed that the planned release date for the regulation would be mid-December, and that a 45-day comment period would follow.

II. Level 2 Consent form for exchange of family member information

Mr. Levin turned to follow up items from the previous meeting. Mr. Dworkowitz explained that the draft Level 2 consent form for the exchange of family member information had been revised since the prior meeting: the option to deny consent had been removed. As a result, patients could withdraw consent simply by making a request in writing over the phone. The title of the form had also been revised in response to suggestions.

Ms. Sutliff said if NYS DOH approved use of the form for this purpose, it could be released to the Qualified Entities (“QEs”) with general guidance. Mr. Kirkwood said NYS DOH would discuss and would get back to the Committee.

III. Community-Wide Consent Language

Mr. Levin indicated that the next issue for discussion was the proposed language in the Policies regarding community-wide consent. Mr. Belfort said the revised language was not intended to be a substantive change since the last version, but instead was intended to eliminate some of the ambiguity that was discussed at the previous meeting. Mr. Belfort walked the Committee through the proposed language.

Dr. Martin said that the revised language was an improvement, but he questioned whether QEs would use a community-wide consent form that did not apply to Part 2 data. Mr. Belfort responded that some QEs are not currently exchanging Part 2 data. But he observed that this would be an issue if some QEs are including Part 2 data and are participating in a statewide exchange. In that case, the technical solution would be to filter Part 2 data and not allow Part 2 data to be exchanged under a community-wide consent form. Dr. Martin replied that if the odds of filtering are near zero, it would make more sense to require community-wide consent forms to be Part 2 compliant.

Mr. Check said Healthix was going to make the community-wide consent Part 2 compliant, but he was reluctant to impose that requirement on other QEs. He noted that Healthix discloses on top of the CCD whether Part 2 data is included, but other QEs do not do that. Ms. Shatzkin said

there could be a danger in leaving this issue to a QE if a particular QE cannot isolate Part 2 data that would be included in a CCD. Mr. Allen said it was technically feasible to identify whether a CCD contains Part 2 data, and that was the type of approach his QE planned to follow. He said that to make the community-wide consent model compliant with Part 2, all participants would have to be listed on the consent form, which logistically is nearly impossible.

Dr. Parsons asked whether providers could comply with Part 2 if they provided a list of potential recipients to patients who request it. Mr. Check said there are options along these lines, such as a forms library that prints on demand, but that they are logistically difficult to implement effectively. Mr. Belfort said guidance from the Substance Abuse and Mental Health Services Administration (“SAMHSA”) says that the name of individual providers need to be included on the consent form and that referencing names on a website is not sufficient, so there is not much flexibility from a legal standpoint.

Mr. Belfort said he thought the only option that is feasible is to filter Part 2 data based on diagnosis codes related to substance abuse. While this would be overbroad, it would prevent Part 2 from being disclosed. Mr. Check said this type of data segmentation is unworkable.

Dr. Parsons said the Committee would not be able to resolve the technical or legal issues, and that the Committee should go to the Greater New York Hospital Association telling them they need to push back if they are unsatisfied. Zeynep Sumer-King, GNYHA representative said she had no problem with that approach and it was just a matter of assisting providers with developing a realistic workflow.

Ms. Shatzkin said the QEs who have decided to exchange Part 2 data have created a problem for the Buffalo QE, which does not have a Part 2 compliant consent. Mr. Belfort said it would be a big problem for Buffalo if the Policies did not give them the option of using a community-wide consent that was not designed for Part 2 data. He said he worked with other clients who think there is a technical solution to segregating such data, and that it should be an option for QEs to determine if they can implement their own technical solutions. Dr. Parsons agreed. Mr. Belfort added that the issue was whether the Policies should give QEs an option or whether the Policies should compel QEs to use a particular consent model, and he is reluctant to eliminate that flexibility. Ms. Shatzkin agreed, saying they needed to leave QEs with some flexibility so that they could come up with creative solutions.

Ms. Sutliff said this proposed language would be put forward as a recommendation to NYS DOH, which would let the Committee know whether its proposal had been accepted.

Mr. Kirkwood noted that some Committee members had suggested that this issue be sent to the implementation committee. He said it would be more useful if they would undertake an educational push about what is feasible given current technology.

Mr. Martin noted that the draft language requires the participant offering a multi-party consent to inform the patient of an option to provide a single provider consent. He asked if there would be a question on the consent form that would confirm that the participant had done this. Mr. Check said he thought this would be problematic in terms of workflow. Dr. Martin suggested that they

add language to the consent form indicating that a single consent form is available. Mr. Check said this suggestion would work fine. Mr. Martin said it is important that the information stand out so that the patient knows there is an option.

IV. Patient Accounting

Ms. Sutliff said that the patient accounting issue needed to be resolved even if there was not total consensus from Committee members.

Mr. Belfort explained that the current version of the Policies gives patients the right to obtain the names of the authorized users who accessed their information through the SHIN-NY, and that some have expressed concern about this policy because it exposes individuals employed by participants to targeting and a loss of privacy. On the other side, Committee members feel that a policy that only allows patients to access the name of a participant and not the name of an authorized user does not provide the patient with much useful information.

Mr. Belfort said the current proposal was an attempt at a middle ground position. Mr. Belfort walked the Committee members through the proposal, under which a participant can either provide a list of authorized users or undertake an audit in response to a request for the names of authorized users.

Ms. Shatzkin said she saw lots of merit to the new language. It would be pretty important to determine how this policy will be communicated to patients, and she suggested that standard language and a standardized communication be developed. Mr. Levin asked where this standard language would be provided. Ms. Shatzkin suggested it be added to QE's websites. Ms. Sutliff questioned whether this is information that should be added to the Policies or whether this is better handled at the implementation subcommittee level. Dr. Martin suggested that the Policies make clear that the patient's right to an accounting should be prominently displayed, and that the consent form, QE websites, and all documents related to patient rights under the SHIN-NY should discuss this information.

Mr. Allen suggested that the language about a "6-year period" should instead say "up to a 6-year period" so as to make clear that a QE or participant did not need to provide 6 years of information if that was not requested.

Mr. Allen questioned what would occur if a participant does an audit and found an inadvertent disclosure, perhaps because the patient had the same name as another patient. Mr. Belfort said he thought this was designed to track the HIPAA framework regarding incidental use.

Mr. Levin said there appeared to be agreement, and that the revised language would be submitted. Dr. Martin asked if the Committee would be able to see the final language, and Mr. Levin said it would be provided.

V. Stakeholder Comments on Version 3.2 of the Policies

Mr. Levin introduced the issue of providing feedback to comments on the Policies. Mr. Allen provided background on his comment regarding Section 6.3 of the Policies, which discusses participant access to audit logs. Mr. Allen read the section and noted that the provision, as written, would allow a participant to access all records of all of that participant's patients. For example, if the participant was a hospital that had medical records of 600,000 people, the hospital could ask a QE to provide a list of every authorized user who ever access the records of those 600,000 people.

Ms. Shatzkin said the genesis of the language was to allow a participant to respond to a patient request for an audit, since the patient would likely go to the participant and not the QE with such a request. Ms. Sutliff asked if this language would also apply to a participant researching a breach. Ms. Shatzkin said it would, and that the purpose of the language was to make sure the data was available to the participant when the participant needed the information; it was not intended to allow a participant to go on a fishing expedition.

Mr. Allen suggested that QEs should only be required to supply the data that the participant itself had previously provided to the QE. Ms. Shatzkin responded that if a patient asked a participant about which other participants had accessed the patient's data, the participant would want to give an answer.

Mr. Belfort said he did not remember what drove this provision, and that it has been in the Policies for years. He said he was not sure if it was driven by breaches because there is a separate section of the Policies that address breaches. He recalled that it was designed to help providers comply with accounting of disclosures, and that if that was the intent it could be narrowed.

Mr. Allen said the provision as written was incredibly broad, and a hospital could use it to gain information on its competitors. Ms. Shatzkin said no one has abused this provision as of yet, but the question is whether they want to take proactive steps to prevent abuse.

Ms. Sutliff said the next comment focused on research. She said the Policies require a committee to review research requests but that the Policies do not require that a QE committee review all research requests. She said the commenters were requesting that all research requests be reviewed by such a committee.

Mr. Check and Mr. Allen both said that their QEs have committees that review research, even if the research involves only de-identified data. Mr. Levin said that if all the QEs are already doing this, then it would not be a burden on the QEs to make this change to the Policies.

Mr. Belfort said that the Policies do not permit research involving identifiable data without patient consent, so that the issue only involves de-identified data or Limited Data Sets. He explained the Policies say that if an IRB takes a position that it does not need to review the research, then the QE should review. Dr. Martin said that policy made perfect sense. He said he assumed that the section is talking about a federal definition of research aimed at increasing generalized knowledge, and that it is not about Quality Improvement which is more individually focused. Dr. Mead said the Committee had carved out a separate area for Quality

Improvement/Quality Assurance. Dr. Martin said the Committee had already worked this issue out.

VI. Life Insurance Proposal

Ms. Sutliff said that the Committee would follow up with John Rodat regarding the life insurance proposal.

VII. Closing and Next Meeting

Ms. Sutliff said she would send out information about the time and date of the next meeting. Mr. Levin closed the meeting.

VIII. Next Steps

- Manatt to revise patient account proposal.
- Document summarizing all proposed changes/additions to the P&Ps by the Policy Committee from December 2014 through October 2015.

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