A meeting of the NYeC Policy Committee was held on July 19, 2017. 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
Nance Shatzkin, Bronx RHIO
Steve Allen, HealtheLink
Tom Check, Healthix RHIO
Amy Warner, Rochester RHIO
James Kirkwood, NYS DOH
Geraldine Johnson, NYS DOH
Christie Allen, NYS DOH
Dierdre Depew, NYS DOH
Jessica Eber, NYS OMH
Roslyn Windhol, NYS OMH
Dr. John-Paul Mead, Cayuga Medical Associates, P.C.
Dr. Glenn Martin, Queens Health Network
Shannon Kinnear, NYSTEC
Maria Ayoob, NYSTEC
Laura Alfredo, GNYHA
Zeynep Sumer-King, GNYHA
Evan Brooksby, HANYS
Valerie Grey, NYeC
Cindy Sutliff, NYeC
Nathan Donnelly, NYeC
Krissy Hines, NYeC
Bob Belfort, Manatt
Alex Dworkowitz, Manatt

The meeting was called to order by Mr. Levin at 11:00 a.m.

I. Welcome and Introductions

Mr. Levin welcomed the Committee members and asked the members to provide any comments on past meeting notes to Ms. Sutliff. Mr. Levin introduced Mr. Kirkwood to provide an update on DOH’s work.

II. DOH Update

Mr. Kirkwood said that DOH was reviewing the update to the policies and procedures that had been submitted by NYeC. He said that it would take a couple of weeks for DOH to approve the
changes and once the changes were approved they would be posted on the DOH website. Mr.
Kirkwood said the new version of the policies would be official as soon as they are posted on the
website.

III. Update on Policy and Procedures Changes Submitted to DOH

Mr. Belfort explained that Manatt had undertaken a comprehensive cleanup of the Policies to
capture the recommended changes to the Policies made by the Policy Committee over the past
year. He said that the changes were not intended to reflect new policy decisions. Mr.
Dworkowitz outlined the changes, explaining they covered areas such as alternative consent
forms, patient care alerts, and clarification of the one-to-one exchange exception.

Mr. Check said that in regards to the alternative consent form proposal, his understanding is that
the Medicaid enrollment form could serve as an alternative consent form, but that the approval of
alternative consent forms is not a signal to QEs that they should abandon existing forms. Ms.
Sutliff and Mr. Levin agreed.

Ms. Shatzkin asked if there was a working group within the state to revise the Medicaid
enrollment form. Mr. Kirkwood said he would have to check with his colleagues in Medicaid.
Mr. Kirkwood said the barrier to revising the form was not a lack of interest, but that the
Medicaid enrollment form cannot be updated all that often.

IV. SAMHSA Meeting Update

Ms. Sutliff said that NYeC, DOH, and Manatt had participated in a phone call with SAMHSA
regarding the new version of the Part 2 final rule. She said the call went well. Mr. Dworkowitz
said there were no major revelations on the call but that SAMHSA was open to listening to
NYeC’s concerns. Mr. Dworkowitz explained that the call addressed several different issues,
including the amount and kind requirement, the use of a general designation on consent forms,
and the definition of qualified service organizations.

Mr. Allen asked why the Part 2 regulations require a treating provider relationship in order for a
general designation to be used. Mr. Belfort said the regulation was premised on an older concept
of the health system where physicians were primarily responsible for a patient’s care.

V. Update on Cybersecurity Assessment

Ms. Sutliff said NYeC was taking steps to implement the cybersecurity recommendations
developed by KPMG. She said the current approach is to develop a Section 10 of the Policies to
standardize an approach to cybersecurity. NYeC will work with a cybersecurity consultant,
William Pelgrin, Partner in Cyber WA, Inc who will provide advice on the scope of the policies
to be included in the Framework.

Mr. Allen asked if HITRUST certification would be sufficient. Ms. Sutliff said HITRUST
certification would be referenced in the Policies, but that such certification is not sufficient
because it does not satisfy all requirements in the NIST framework. Ms. Kinnear said NYSTEC
was working on a crosswalk between the NIST framework and the HITRUST requirements which likely would be completed in four to six weeks.

VI. Access v. Disclosure

Mr. Belfort explained that the original model for the SHIN-NY was focused on participants pulling information, and that the Policies were written with a data access model in mind. However, that has been supplemented by a different model under which QEs play a more active role in organizing information and pushing it out to providers, and the Policies have not kept up with this paradigm shift.

Ms. Sutliff said this is just the beginning of the discussion and that the aim of the day’s conversation was to allow the development of more detailed proposals for an in depth discussion at the Committee meeting in September.

Participant Right to Disclosures

Mr. Dworkowitz asked: if a participant is allowed to access data through the SHIN-NY, should that participant always be allowed to receive the same data via a disclosure from the QE? Mr. Allen said it may depend on who is making the decision: the recipient of the data or the supplier of the data. In the case of a query, the recipient makes the decision. In the case of disclosures, there can be a standing query for information in which the recipient makes the decision, but there can also be cases where the data source instructs the QE to push data to other participants.

Mr. Check said that in the case of Healthix, the majority of data that is disclosed is done with written patient consent and very little is done under a consent exception. Dr. Martin said he was not sure there is much of a difference between a push and a pull so long as the patient has consented.

Mr. Dworkowitz asked if it made sense to allow a push in a break the glass scenario. Mr. Allen said he thinks it would be okay, although he has not seen a lot of requests for this type of thing. Ms. Shatzkin said if the emergency was over, then the QE would no longer be able to do the push. She said it was hard to imagine a push in the break the glass scenario. Mr. Check said it was the practitioner’s judgment as to whether an emergency condition exists, and it is not possible for a QE to have a logic to make a judgment call.

Non-Participant Right to Disclosures

Mr. Dworkowitz asked if a patient should be able to disclose to anyone in the universe with consent. Mr. Check said that if a recipient is not a participant, the challenge is that there needs to be a contractual relationship that will require the recipient to comply with certain standards, such as to only use the data for purposes allowed in the agreement with the patient.

Ms. Shatzkin said she would assume that the QE would need to see the consent form from the third party and not take it on faith that the third party could have consent. Mr. Check said the QEs could perform an audit. Ms. Shatzkin said her gut reaction is that there are two categories,
one where the QE knows the organization and trusts them, and the other where it is a one-off request from an organization or person that the QE does not know. She said in the latter situation she imagines the QE would need to see the consent form. Dr. Martin asked if any medical records offices currently accept an assertion that patient consent exists. Mr. Check said this is similar to the way Healtheway works: under Healtheway, a QE must have an agreement in place with Healtheway to share and receive data, and when a provider requests information from Healtheway there is no requirement to provide additional documentation.

Mr. Dworkowitz asked if there are any types of entities, such as life insurers, which should not be able to receive disclosures. Mr. Dworkowitz noted that a life insurer could pressure a patient to sign a consent form. Ms. Eber said this was similar to the Medicaid enrollment form, which was also a contract of adhesion. Dr. Mead said the two were different, since one was a health insurance contract.

**Disclosures and Audit Logs**

Mr. Dworkowitz asked if both pushes and pulls should be recorded in audit logs. Ms. Shatzkin said she assumed that pushes are auditable, and that if you are a patient you deserve to know if an alert was pushed. Mr. Allen questioned if this would include one-to-one exchanges. Ms. Shatzkin said a one-to-one exchange seemed different, since in that case the QE was acting as a post office and was not the primary source of data. Mr. Belfort said a distinction could be made between a QE serving as a pipe or in a more substantive role, but he suggested there might be one-to-one exchanges where a QE is not just a conduit but is playing a more active role in pulling records. Mr. Check agreed, and said Healthix does have an active role for certain one-to-one exchanges and keeps an audit log for such exchanges.

Ms. Shatzkin said the issue is whether the sender has no means of providing the information. She said in some cases, such as the sending of an alert, the only party that is in a position to track the data is the QE, and that differs from a results delivery situation.

Mr. Belfort noted that there is no duty for the receiving party to notify the patient of the disclosure unless the Policies are revised to create such a duty, since such notification is not required under the HIPAA accounting rules.

**Disclosing to Non-Authorized Users**

Mr. Dworkowitz asked whether individuals who are non-authorized users should be allowed to receive disclosures sent to Participants. Ms. Shatzkin said her QE had discussed this issue and they had come to the conclusion that those who receive analytics output should be required to undergo training. Mr. Allen said this was similar to the concept of a certified application. Mr. Check said once a record is in an EMR, subsequent people can access the EMR, and they are not authorized users. Mr. Allen said they would be authorized users of the EMR but not authorized users of the QE. Mr. Allen said QEs are only training people who are authorized users, those who have the power to access the system.
Mr. Allen said that a minimum, if the person is a workforce member of a participant, HIPAA will apply. Mr. Allen said his gut reaction is that the participant should be accountable for making sure any workforce members are accessing information appropriately.

Mr. Dworkowitz asked if a life insurer should be required to go through training. Ms. Shatzkin said she did not see why a life insurer should be required to go through training, since they would be providing the information at the request of the patient, not at the request of the life insurer.

Mr. Levin said that this was the first round of discussions on this issue, and that they would attempt to narrow the framing of these questions in advance of the September face-to-face meeting.

VII. Number of patients for research

Ms. Sutliff introduced Mr. Check to discuss his proposed change regarding research. Mr. Check said that in some cases, there may be a research study that is in its design phase, and the researcher is trying to determine what the qualification criteria should be. The researcher may want to know whether the inclusion criteria will result in a reasonable number of patients. Under the proposal, the researcher would be able to receive a count of patients meeting the inclusion criteria without patient consent.

Mr. Allen said the researcher would not be receiving de-identified data and would just be receiving metrics. Ms. Sumer-King asked if the recipients of the data would be participants. Mr. Check said it was up to the QE as to whether they would be participants or non-participants.

Dr. Martin said he was concerned about the definition of research, and asked whether market research would qualify as research. He said Mr. Check’s proposal did not create this problem but it would nice to know if this question was being properly handled.

Mr. Check noted that this research would occur prior to IRB approval, since it is impossible to have IRB approval at so early a stage.

VIII. Closing

Mr. Levin thanked the group for their time and said they would be in touch about scheduling the September meeting.