New York eHealth Collaborative Policy Committee Meeting
August 13, 2015
9:00 a.m. – 11:00 a.m.
Meeting Notes

A meeting of the NYeC Policy Committee was held on August 13, 2015. Present either in person or via telephone were:

David P. Martin, Consumer Health Care Advocate
Dr. Thomas Mahoney, Finger Lakes Health Systems Agency
Nance Shatzkin, Bronx RHIO
Dr. Amanda Parsons, Montefiore
Ronnie Pawelko, JD, Family Planning Advocates of NYS
Steve Allen, HealtheLink
James Kirkwood, NYS DOH
Jonathan Karmel, NYS DOH
Dr. John-Paul Mead, Cayuga Medical Associates, P.C.
Dan Tietz, AIDS Institute
Dr. David Cohen, Maimonides Medical Center
Dr. Glenn Martin, Queens Health Network
Paul Schaeffer, NYCDOHMH
Geraldine Johnson, NYS DOH PH Informatics
Christie Allen, NYS DOH
Ted Kremer, Rochester RHIO
Tom Check, Healthix RHIO
Laura Alfredo, Greater New York Hospital Association
Susan Van Meter, Health Care Association of New York State
Colleen Mooney, NYSTEC
Cindy Sutliff, NYeC
Inez Sieben, NYeC
Vinay Chopra, NYeC
Bob Belfort, Manatt
Alex Dworkowitz, Manatt

The meeting was called to order by Ms. Sutliff at 9:00 a.m.

I. NYS DOH Update

Ms. Sutliff introduced Mr. Kirkwood from the New York State Department of Health ("NYS DOH") to discuss the draft SHIN-NY regulation. Mr. Kirkwood said that the regulations had not yet been released for public comment. He said that there have been some personnel changes in the NYS DOH counsel's office, so NYS DOH was still going through the regulations internally. Ms. Sutliff asked Mr. Kirkwood if he had a sense of when the regulations would be released for public comment, and he said that he did not.

Mr. Kirkwood said that NYS DOH was addressing many issues related to the Delivery System Reform Incentive Payment ("DSRIP") program, including sending an opt-out letter to beneficiaries in September and educating Performing Provider Systems ("PPSs") about what is occurring. Ms. Shatzkin said that PPSs can't share data outside the PPS prior to the completion of the opt-out period, and Mr. Kirkwood said that this is correct.

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

Ms. Sutliff said that a Level 2 consent form for the exchange of information about a patient's family member had been revised in light of past Committee discussions. Mr. Belfort said that the changes were designed to incorporate previous comments received. Mr. Dworkowitz explained the changes to the form, including the requirements that the form be notarized if signed outside the presence of a participant and that the form notify family members of the potential for their patient to see their information. Ms. Sutliff added that the Policies should be revised to reflect rules related to the use of this form.

Mr. Martin asked how a provider would be able to know that information in a patient's record related to the patient's family member and not the patient. Ms. Shatzkin said that if this was a concern, then the most effective person to speak to about this would be the provider, and that the provider could note the issue in the chart. Mr. Martin observed that if the family member's information was in the patient's record, this information could be included in the information sent to an insurer to explain why tests are being run. Dr. Mahoney agreed that, for example, a positive family history of breast cancer could be part of a prior approval process. Dr. Mead said he agreed that it made sense to allow a conversation between the provider and family member about the issue, but he said that once the family member's information is in the record operationally it has to be released to the patient. Dr. Mead said that if the family member does not want the patient to learn about the family member's medical information, the best way for the provider to handle this is to keep that information out of the patient's file altogether.

Dr. Mahoney said that this question was theoretical, since if the family member did not want the patient to find out about the family member's information, why would the family member share that information with the patient's provider? Mr. Martin said there would be cases where the family member does not want the patient to know, but he agreed that often this would not be an issue. Mr. Belfort noted that the consent is voluntary, and if the family member is concerned about the possibility of the patient finding out about the family member's medical information the family member does not need to sign.

Ms. Shatzkin said that leaving a blank on the form regarding a time limit on access could be an implementation challenge, and that she is not a big fan of forms that can be filled in by sloppy handwriting. Dr. Parsons suggested that they could put in bubbles like a scantron form. Dr. Parsons also said she thought it should only be one-time access since there is no need for ongoing access. Ms. Shatzkin and Ms. Sutliff agreed. Mr. Allen said the time limit is a decision that a Qualified Entity ("QE") would make on a case by case basis. Mr. Belfort said the Policies could give QEs flexibility, such as by proposing a time limit not to exceed a certain amount. Dr. Parsons asked if different time limits by different QEs would be an issue in cases of a cross-QE

lookup; Ms. Shatzkin said this would not be an issue. Ms. Sutliff said the language in the form would be adjusted accordingly to give QEs more flexibility.

Mr. Allen asked if he could send the draft form to a provider interested in undertaking such an exchange. Mr. Belfort said the form was consistent with the current version of the Policies, so it could be shared. Ms. Sutliff asked Mr. Kirkwood if he had any concerns about this, and Mr. Kirkwood said he had no concerns at the moment.

III. Community Wide Consent Notice Requirements

Mr. Belfort said that an earlier draft of the SHIN-NY regulations provide for notice to accompany community-wide consent, and that some thought it would be helpful to better define what form of notice is required. Mr. Belfort said the tenor of the previous discussions was to provide notice but not to make this task burdensome. Based on these discussions, Mr. Belfort said the proposal requires QEs to provide updates on their websites within 24 hours of a participant joining, that QEs would be required to provide hard copy list of participants upon request, and the community-wide consent form would notify patients about this process. Mr. Belfort said that an annual notice requirement was previously discussed, but this has not been included in the proposal.

Mr. Check said he thought the proposal was doable. However, he said an annual notice requirement was not implementable—there are three million consents and contacting all of those people is not achievable.

Mr. Martin said if community-wide consent is going to be so broad, there should be a requirement up front to make sure that it is informed consent. He noted that a lot of people do not have digital access, so there needs to be an option to get that information through the mail. Mr. Martin said he did not see a turnaround time for sending out mailings, and that such a time limit should be included in the proposal. He also said that the thought an annual notice was needed as a reminder to patients that they have agreed to a community-wide consent.

Mr. Allen said they would be concerned operationally about doing an annual notice, either electronically or through a mailing. Ms. Shatzkin noted that the QEs do not have patients' contact information. Mr. Allen said there are significant costs to sending notices through the mail; Mr. Kremer said he did not see how an annual notice would work. Ms. Shatzkin said that patients who sign up for community-wide consent are walking down a different path, and that these patients are generally more comfortable with their information being shared than other patients. Ms. Sutliff said that this is not a perfect system, and while privacy needs to be maintained, they need to also consider the burden of requirements. Mr. Allen said it was not uncommon for his QE to receive a phone call from a patient asking whether they signed a consent form, and that the QE has an obligation to provide that information.

Mr. Belfort said he agreed with Mr. Martin's point that consent needs to be informed, and therefore no patient should be offered only a community-wide consent choice.

Mr. Karmel said that alternative language in the regulations says that the QE must document that it periodically notifies the patient or the patient has declined the opportunity to receive notice. He said that patients should have the right to share their information if that is what they want to do. He said he understood that a lot of people do not have internet access, but people can go to the public library and get internet.

Mr. Check said that an annual notice system would be easier to implement if the default choice was not to receive notification. Mr. Belfort said that in the current proposal, there is no notification, so there is nothing to opt out of.

Mr. Allen said that he spends a lot of time every week unsubscribing from emails, and that he is therefore not a fan of automatic notice. He said that in his QE's experience, less than 10 percent of the patients are interested in staying informed. He said if that if a patient wanted to opt-in to annual notice, a patient could sign up for notifications on a QE's website by supplying an email address.

Mr. Martin stressed that informed consent was needed, and also a time frame as to when mailings need to be sent out. Ms. Sutliff said that policies around informed consent are already in place. Mr. Check said he agreed with Mr. Martin and said that the hard copy list should be mailed within 5 days of a request.

Ms. Shatzkin questioned whether it was feasible to update the website within 24 hours of when a participant joins a QE, since in some cases there may be a gap between when a participant joins a QE and when a participant actually is able to access information through the QE. Mr. Belfort said that this can be revised to say that the website must be updated within 24 hours of when a participant can access information through a QE.

Ms. Sutliff said that the Committee seemed to agree that the proposal was acceptable, but the Committee also agreed that the annual notification requirement was too burdensome and should not be included in the proposal. She said the proposal would be revised.

IV. 42 CFR Part 2 and Community Wide Consent

Mr. Belfort explained that when developing the Policies, NYS DOH reached out to the Substance Abuse and Mental Health Services Administration ("SAMHSA") regarding information subject to 42 CFR Part 2 and health information exchanges. In FAQs, SAMHSA indicated that a reference to a class of providers in a consent form would not be adequate, in contrast to HIPAA and state laws.

Mr. Belfort said the simplest way to deal with Part 2 was to continue to use a single consent form option, but there are downsides to this. Mr. Belfort said that if they did use a community-wide consent form, QEs would need to ensure that the form would not allow access to Part 2 data and QEs would also need to have the technical ability to ensure that Part 2 providers who later join the QE would not be able to rely on the community-wide consent.

Mr. Check said that Healthix is not going to implement a community-wide consent model that allows future participants to access information. He said it was very important for the QE to make the entire patient record available, including Part 2 data. Dr. Parsons said that practically speaking, every single provider will be getting their own consent form. Ms. Shatzkin said that the QEs are currently in a period of growth, and therefore a community-wide consent model that included only current participants and not future participants would be more valuable to QEs once the period of growth slowed down.

Ms. Shatzkin asked why there were only concerns regarding access and not disclosure. Mr. Belfort said it comes from SAMHSA's interpretation of old regulations, which require more specificity for those receiving the information than for the person making the disclosure.

Ms. Sutliff said she heard there were discussions at the federal level about possible changes to these rules. Ms. Susan Van Meter from HANYS said she heard from a SAMHSA staff member that there would need to be a change in the law in order to obtain the flexibility that was sought. Ms. Laura Alfredo from GNYHA said there does seem to be some resistance to loosening up the consent requirements, although more voices explaining the obstacles might be of some help. Ms. Sutliff indicated that some of these issues had already been brought to SAMHSA's attention and that it might be worth considering another round. Ms. Van Meter said she would be happy to continue the conversation, but opposition from privacy groups would make it more challenging. Mr. Karmel said the more obvious strategy would be to make the technology conform with the law. Ms. Sutliff said the issue is how to segment the data, and that if the resources that are required to make the technical changes were readily available and there was a will on the part of EHR vendors to change perhaps that might be possible. Given, however, the current environment, the QEs are faced with coming up with solutions that may not be what we would want to see in a perfect HIE world.

V. Comments on Policies

Ms. Sutliff said that the Committee should develop comments on the revised Policies issued by NYS DOH. She said that NYeC staff will draft comments based on prior Policy Committee discussions that will be sent to the Committee for review.

Mr. Belfort noted that in terms of governance, the revised Version 3.2 of the Policies delete references to the State Designated Entity and the Policy Committee. Mr. Belfort also observed that the new version of the Policies revised the provision on one-to-one exchanges to make it easier for health plans to get patient information without patient consent. He said that overall, the changes in Version 3.2 were fairly modest.

Ms. Sutliff said that the comment period will end on August 31, and that comments will go out as a unified comment from the Policy Committee. Mr. Kirkwood said that it is similar to rulemaking activity in that they are expected to show all comments they receive, and if there are similar comments they will be lumped together.

VI. Patient Accounting

Ms. Sutliff said the Committee was stuck on the issue of whether a patient should have access to authorized users' names in seeking an accounting.

Mr. Allen said he recalled the Committee discussing the possibility of a small group getting together to come up with a compromise. Ms. Sutliff said they had talked about that possibility early on. Mr. Allen said he did not think they could get a consensus on just dropping the requirement to provide the name of the authorized user.

Mr. Martin asked if there was a check and balance already in place to audit access. Mr. Belfort said there is the framework under HIPAA, which requires providers to have internal controls. In addition, patients can file complaints and providers are supposed to investigate those complaints.

Mr. Allen said the Policies could give patients the right to initiate an audit at a particular participant, and the outcome of the audit would be either a determination that there was no impermissible access or a determination that there was impermissible access. Mr. Martin said a patient might suspect there is a breach, but may lack the grounds to file a complaint. Ms. Shatzkin said that under this proposal, there would not need to be any standard to meet in order to request an audit—it could be based simply on a hunch or a curiosity.

Mr. Kremer said that he has heard concerns from a hospital about listing names of authorized users, but doing so has put them in a stronger place to enforce their policies. He said that in one recent incident, a patient had a concern that a particular user was accessing information that was not appropriate, and it turned out that the consent was not turned off when a person left the practice at issue. Mr. Kremer said being able to hold the policy to participants was useful.

Mr. Allen said that probably a small fraction of access would occur through a QE, and most would occur through a hospital system. Dr. Mahoney said he viewed it as a request as to whether a QE has been accessed improperly.

Ms. Sutliff said it looked like the Committee was still unable to reach consensus on this issue and that a small group would be convened to come back to the Committee at the September meeting with a proposed approach.

VII. Next Steps

- Manatt to revise Level 2 consent form for sharing of family member information.
- Manatt to revise proposal for community-wide consent notice.
- NYeC/Manatt to draft comments on Version 3.2 of Policies.
- Small group to develop patient accounting proposal.