

**New York eHealth Collaborative Policy Committee Meeting**  
**April 14, 2015**  
**9:00 a.m. – 12:00 p.m.**  
**Meeting Notes**

A meeting of the NYeC Policy Committee was held on April 14, 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  
Irene Koch  
Steve Allen, HealthLink  
James Kirkwood, NYS DOH  
Paul Schaeffer, New York City Department of Health and Mental Hygiene  
Linda Adamson, NYCDOHMH  
Dr. David Cohen, Maimonides Medical Center  
Ted Kremer, Rochester RHIO  
Tom Check, Healthix RHIO  
John Rodat, Public Signals, LLC  
Gus Birkhead, NYS DOH Office of Public Health  
Corinne Carey, NYCLU  
Dr. Amanda Parsons, Montefiore  
Steve Allen, HealthLink RHIO  
Geraldine Johnson, NYS DOH Public Health Informatics  
Cindy Sutliff, NYeC  
Inez Sieben, NYeC  
Vinay Chopra, NYeC  
Bob Belfort, Manatt  
Susan Ingargiola, Manatt  
Pat Roohan, NYS DOH  
James Kirkwood, NYS DOH  
Joseph Anarella, NYS DOH  
Jonathan Karmel, NYS DOH Legal Counsel

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. Kirkwood, Mr. Roohan and Mr. Karmel from the New York State Department of Health (“NYS DOH”) to discuss the updated draft SHIN-NY regulation. Mr. Levin said that the goal of the meeting is to understand how the updated draft regulation will affect the work of the Policy Committee, including how the

Committee will interact with NYS DOH. Mr. Levin reminded everyone that, after finalizing the draft regulation, NYS DOH will release it as a proposed regulation for formal public comment.

## **II. NYS DOH Update and Discussion of Updated Draft SHIN-NY Regulation**

Mr. Roohan briefly described NYS DOH's rationale for updating the draft SHIN-NY regulation. He said that the proposed changes to the draft regulation are the result of many factors, including the need to develop an ongoing governance process for the SHIN-NY that will continue to function in the absence of state funding. He said that one of NYS DOH's goals was to streamline the regulation and make it simpler. He also explained that the SHIN-NY policy standards will no longer be incorporated by reference into the regulation. He then introduced Mr. Kirkwood.

Mr. Kirkwood said that NYS DOH streamlined the language in the regulation that describes the process by which policies governing the SHIN-NY will be developed. The new language is intended to make clear that NYS DOH is the owner/curator of the Privacy and Security Policies and Procedures (the "P&Ps") as well as other SHIN-NY policy standards. NYS DOH will look to the Policy Committee to identify changes/additions to the P&Ps. But the Policy Committee will no longer be responsible for editing the P&Ps. NYS DOH will draft edits to the P&Ps (or choose not to make any changes at all) in its sole discretion. Mr. Kirkwood said that NYS DOH may release the P&Ps for public comment once per year. This process is designed to be similar to the federal process used by FACA committees. NYS DOH will make agendas and minutes and recommendations available to the public.

Mr. Kirkwood explained that by removing the SHIN-NY policy standards, including the P&Ps, from incorporation by reference into the regulation, NYS DOH will have more flexibility to update the P&Ps without having to go through the formal SAPA process.

Several committee members asked how compliance with the P&Ps will be enforced if the P&Ps are no longer incorporated by reference into the SHIN-NY regulation. Mr. Karmel said that while the P&Ps will not have the weight of law, compliance will continue to be mandated contractually (i.e., through contracts between NYeC and the State, between NYeC and the qualified entities (QEs), and between QEs and their participants). Mr. Karmel also pointed to the existence of certification requirements, which QEs must satisfy as a condition of participation in the SHIN-NY. Several committee members pointed out that the certification requirements do not currently incorporate all of the requirements in the P&Ps.

Mr. Karmel noted that QEs and their participants will still have to comply with the NY Public Health Law and the NY Mental Hygiene Law as well as other applicable privacy laws. Mr. Belfort pointed out that there is a lot of ambiguity in these laws, which has led to significant confusion about how to implement those laws in the context of electronic HIE. This confusion is what led to the development of the P&Ps, which are designed to provide additional rules to guide health care providers as they share information electronically through the SHIN-NY. Mr. Belfort agreed that removing the P&Ps from incorporation by reference to the draft regulation will provide more flexibility to change them as necessary. However, he stressed the importance of not merely dictating that QEs and health care providers comply with NY's ambiguous privacy laws but rather providing some additional guidance in the form of the P&Ps.

Dr. Martin asked whether, under the updated draft regulation, a group of health care providers could create a private HIE that does not connect to the SHIN-NY and operate it without having to be in compliance with the draft regulation or the P&Ps. The group agreed that the answer is yes.

Ms. Carey said that it seems as though NYS DOH is saying that it is too complicated to revise/clarify NY's privacy laws so that they account for electronic HIE so instead the updated draft regulation merely requires QEs and participants to (i) determine what existing law says; and (ii) comply with it. She said this is concerning.

### **III. Updated Regulation Review and Discussion**

Ms. Sutliff introduced Mr. Belfort to walk the Committee through the major Policy-Committee-related changes in the new draft regulation. Mr. Belfort said that the first major change relates to the process by which the regulation and the P&Ps will be updated, as described above. Mr. Kirkwood said that NYS DOH eliminated much of the detailed language relating to the process by which the Policy Committee develops recommended changes to the P&Ps from the regulation because it was unnecessary.

Mr. Belfort said that the second major change is the fact that the SHIN-NY policy standards, including the P&Ps, are not incorporated by reference into the regulation. Pursuant to this change, NYS DOH made several conforming changes to Section 300.5 of the draft regulation. The previous draft regulation provided that patient information could be exchanged through the SHIN-NY consistent with the P&Ps. The updated draft regulation provides that patient information can be exchanged solely for purposes authorized by state and federal law. Thus, the updated draft regulation defaults to compliance with underlying law. As noted above, the challenge with this is that there is a significant amount of confusion about what existing law means in the context of electronic HIE. Thus, additional standards, such as those in the P&Ps, may be necessary to enable QEs and health care providers to exchange information in a uniform manner.

Mr. Belfort pointed out that NYS DOH appears to have attempted to authorize a "community-wide consent model" which would allow a patient to sign a single consent form that would authorize sharing of his or her information among all QE participants current and future. The participants would not all have to be named in the authorization form so long as the patient was notified when new participants became part of the QE. Mr. Belfort said that it would be helpful to provide additional guidance (e.g. in the P&Ps) about what would constitute effective notice since this is an issue on which QEs and participants could have differing opinions.

Ms. Shatzkin noted that the community-wide consent model that NYS DOH included in the updated draft regulation may not comply with 42 CFR Part 2 or with Article 27-F of the NY Public Health Law. Mr. Belfort explained that SAMHSA released a FAQ that provides that a consent form authorizing disclosure through a QE cannot merely authorize all current and future participants to access patient health information. It must list them each by name. Thus, the

Policy Committee was functioning under the impressions that QEs and participants would have to withhold Part 2 data from exchange if a community-wide consent model was employed. The Committee has the same concerns about confidential HIV related information.

Mr. Belfort noted that the updated draft regulation appears to provide that health care practitioners can exchange patient information through the SHIN-NY without patient consent if they have previously obtained patient consent under Section 6530 of the NY Education Law, which is a provision in the professional misconduct statute that says practitioners can't reveal personally identifiable information without the patient's consent except as permitted or required by law. He and several Policy Committee members asked NYS DOH for clarification of the relationship of Section 6530 to the consent required for electronic health information exchange through the SHIN-NY. Mr. Belfort noted that consent under Section 6530 does not have to be written; it may be verbal. Thus, because the updated draft regulation does not mandate a particular form of consent for exchange of patient information through the SHIN-NY and merely says that participants can disclose patient information without written consent only as allowable under existing law, practitioners could interpret the updated draft regulation to mean that if they have a patient's verbal authorization to disclose information under Section 6530 of the Education Law, they may exchange that patient's information through the SHIN-NY without further consent from the patient. Ms. Carey said she would interpret the provision to mean the opposite. Mr. Karmel said that the provision was meant to provide that if a practitioner has a written consent from a patient that meets standards similar to that required for disclosure of confidential HIV information, then the practitioner can disclose patient information through the SHIN-NY without further consent. Mr. Karmel agreed to make that more clear in the draft regulation.

Mr. Karmel also noted that it may be a good idea to include a requirement that QEs and participants use a standardized consent form to obtain patient consent to exchange health information through the SHIN-NY.

Mr. Karmel noted that another major change from the previous regulation was NYS DOH's inclusion of language providing that participants may but shall not be required to subject sensitive health information to certain additional requirements, including but not limited to obtaining a patient's consent before uploading the information to a QE. Ms. Carey asked if NYS DOH was suggesting that it "would be wise" to obtain a patient's consent prior to uploading the patient's information to a QE. Mr. Karmel said that participants should continue to use their judgment to determine whether to obtain a patient's consent to upload the patient's health information to a QE based on their interpretation of State law.

Mr. Belfort noted that NYS DOH removed Section 300.6 from the updated draft regulation. Section 300.6 set forth various rights of patients to, among other things, access their own health information and know who accessed their information through the SHIN-NY. Mr. Martin voiced concern about the removal of this section. Mr. Karmel said that the access provisions in the P&Ps will still be enforced by contract but if there is a strong feeling from the group that reference to patients' rights should be included in the regulation, NYS DOH will consider adding it back in.

Mr. Belfort pointed out that there are no federal or state laws that mandate that QEs aggregate the records of all the participants in the QE and provide that aggregated information to the patient. While this requirement is in the P&Ps, it would be important to have at least a reference to some basic patient rights, such as access to their information and access to an accounting of who accessed their information through the SHIN-NY, in the regulation as well.

Mr. Martin noted that using the SHIN-NY to disclose patient health information across state lines could be dangerous to certain groups of people owing to laws in certain states (e.g. Indiana, which has a law that enables discrimination against individuals based on sexual orientation). Several Committee members pointed out that because the SHIN-NY policy standards provide that a patient must provide consent before his patient health information may be accessed through the SHIN-NY, no health care provider in Indiana would be able to access a NY patient's records through the SHIN-NY without his consent.

Mr. Martin also inquired about who may access a patient's medical records after they die. Mr. Karmel noted that under NY PHL 18, the personal representative of a deceased person's estate may access his or her health information or, if no such personal representative exists, a distributee under the NY EPTL may do so.

Dr. Martin pointed out that the language in Section 300.3 of the updated draft regulation uses the word "may" instead of "shall" when referring to whether NYS DOH must establish workgroups, forums, and committees to develop and make recommendations on SHIN-NY policies, and technical standards etc.

#### **IV. SHIN-NY Policy Issues Currently on Agenda**

Ms. Sutliff provided the Committee with an update on the status of several policy issues on the Policy Committee's current policy agenda.

##### *a. Patient Access to Audit Records of Who Has Accessed Their PHI*

Mr. Levin recommended a joint meeting of the Policy Committee and the BOC to address this issue. He noted that it is very important for patients to be able to know in real time who has accessed their records through the SHIN-NY so they can raise questions. Mr. Allen agreed and noted that the thorny issue here is the level of granularity to include in the audit (i.e., should patients be given the name of every individual practitioner who accessed their information).

##### *b. Payer Access to SHIN-NY*

Mr. Kirkwood explained that NYS DOH is contemplating whether it is possible to treat access by payers for HEDIS measurement purposes as a one to one exchange (recognizing, however, that QEs, participants and payers will still have to comply with laws enabling patients to request that information about sensitive services for which they paid out of pocket be shielded from access by payers). Committee members agreed that complying with this requirement is a big operational challenge for QEs. Mr. Kirkwood said that NYS DOH will be asking for comment on how to address this issue. Ms. Sutliff noted that the Implementation Subcommittee has begun

discussing this issue as well and to put it on the agenda for the full Policy Committee after the issues of community-wide consent and patient access to audit records are addressed.

*c. Community Wide Consent Model*

The Committee agreed to address this issue at its next meeting, recognizing that how the Committee proceeds will depend on what NYS DOH ultimately includes in the draft regulation on this issue.

*d. Minor consent*

Ms. Sutliff provided an update on the work of the Minor Consent Tiger Team. She said the team will meet this Friday to review the Let the Data Flow model again and to develop a charge for a new subgroup to create implementation guidance.

*e. Cross QE Alerts and Notifications*

The Committee agree that a separate consent is not necessary for cross QE alerts and notifications so long as the QEs sign bilateral agreements in which they agree to abide by the SHIN-NY policy standards.

*f. Implementation of Research Level 2 Form of Consent*

Ms. Sutliff said that the Tiger Team created a L2 form of consent for research which will be used in a pilot program offered in Buffalo. Mr. Allen said he will be moving the pilot forward shortly.

*g. Patient Portal update: ID Proofing and Immunization Integration (Release 2)*

Ms. Shatzkin noted that there are several portal-related issues (e.g., education, patient authentication, integration of immunization information) that have yet to be addressed. Further, health care providers may be reluctant to support QEs having their own portals. The Committee agreed that this should be put on the Committee's calendar toward the summer (after the NYeC portal pilot gets up and running).

**V. Next Steps**

The Committee agreed to create a list of items that NYS DOH will consider before it finalizes its updated draft of the regulation and releases it for public comment. The Committee also agreed to discuss the community-wide consent model and patient rights/accounting of disclosure issue at its next meeting. Finally, the Committee agreed to review the updated draft regulation and the updated P&Ps (both as released by NYS DOH) at the upcoming face to face meeting in June.

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