**Steering Committee Meeting Minutes**

**May 3, 2018**

# Meeting Participants

| **Committee Members** |
|---|
| ✓ Nancy Beavin, Humana<br>Bill Beighe, Santa Cruz HIE<br>✓ Hans Buitendijk, Cerner<br>✓ Michael Hodgkins, AMA<br>✓ Kevin Isbell, Kaiser Permanente<br>✓ Leslie Kelly-Hall, Healthwise<br>✓ Andrew Kling, Geisinger<br>✓ Rob Klootwyk, Epic<br>✓ Steven Lane, Sutter Health<br>✓ Kathy Lewis, Surescripts<br>✓ Tushar Malhotra, eClinicalWorks<br>Geoff Lay, GE Healthcare<br>Aaron Seib, NATE<br>✓ Ryan Stewart, Dignity Health<br>✓ Steve Bounds, SSA (Ken Pearlstein for Steve Bounds) |
| **Invited Subject Matter Experts and Carequality Support Team** |
| ✓ Dave Cassel, Director, Carequality<br>✓ Chris Dickerson, Program Coordinator, Carequality<br>✓ Mariann Yeager, CEO, The Sequoia Project<br>✓ Eric Heflin, CTO/CIO, The Sequoia Project<br>Didi Davis, Testing Programs Director, The Sequoia Project<br>Jennifer Rosas, eHealth Exchange Director, The Sequoia Project<br>Dawn Van Dyke, Marketing Director, The Sequoia Project<br>Kati Odom Bell, eHealth Exchange Implementation Manager, The Sequoia Project<br>✓ Alan Swenson, Kno2<br>✓ Morgan Knochel, OneRecord<br>✓ Bill Mehegan, The Sequoia Project |

# Meeting Summary

## Call to order *12:34pm EST*

***Discussion Summary:*** Roll call was facilitated, and a formal quorum was established. The agenda was discussed.

***Decision/Outcome****:* The agenda was reviewed, and nothing was added.

***Action/Follow up****:* None.

### Agenda

- *Roll Call*
- *Agenda Review*
- *Admin Items*
  *– Meeting Minutes*
  *– Welcome Geoff Lay!*
  *– Advisory Council seat*
- *Advancing Patient Queries - Recommendations*
- *Production Operations Update*

## Administrative Items

**Minutes of the Last Meeting**

***Discussion Summary:*** The April minutes were introduced, and a motion was made by Hans and seconded by Kathy to approve the April minutes.

***Questions/Discussion****:* All members approved with no objections.

***Action/Follow up****:* The April minutes were approved.

**Welcome!**

- Geoff Lay is taking up the GE Healthcare seat originally held by Mark Segal

***Discussion Summary:*** Geoff was unable to attend this meeting but is welcomed by the committee!

***Questions/Discussion****: n/a*

***Action/Follow up:*** *n/a*

### Advancing Patient Queries - Recommendations

Working Group Background

The working group had the following goals:

- Determine what, if any, roadblocks exist that prevent Implementers and CCs from honoring patient generated queries
- Investigate what technical gaps exist in policy and technology and how might we address them
- What role Carequality can play in ensuring that these queries are honored by Implementers and CCs

***Discussion Summary:*** Dave commented advancing patient queries working group had the goal of identifying, exploring, what challenges or roadblocks existed that prevents Carequality implementers and connections from honoring patient requests, queries for the patient request permitted purpose and identify any technical gaps that existed, any policy gaps, and what, if anything, Carequality could do to address any identified challenges. The group met off and on in spurts over the course of almost a year and did identify a few challenges and proposed steps to mitigate them.

**Conclusions**

- We identified several challenges, and have proposed steps to mitigate them
  – Releasing different document content to patients relative to what is released to provider organizations or other requesters
- Proposed mitigation
  – Clarify in implementation guide that this is permitted
  – Concern from providers that the patient will not understand how their information might be used or further released by a PHR or consumer app, AND might seek to hold the original releasing provider responsible for any mishandling
- Proposed mitigation:
  – Place specific data transparency requirements in implementation guide, relying on HHS' Model Privacy Notice (MPN)
  – Require that terms and conditions for use of the app/PHR clarify that responsibility for information is the patient's
  – Update the Carequality Implementer Application process to confirm compliance with updated requirements

***Discussion Summary:*** Dave commented that the first challenge that was identified was there is often different content in some examples there might be content that is not always released to the patient, but generally released different content to patients relative to what's released to provider organization. A few specific examples were states with particular laws around STD results, for example, that could not be released to the patient electronically as the initial way that they were released. There were some other cases where a patient might get more than a provider would, in the realm of behavioral health and others where there are authorization and consent considerations, but if the patient themselves requested the info, it would be provided to them. There may be different content released to the patient than there is to the provider. This could even be as simple as just having more patient-friendly language for some of the terms in a problem list or meds list. That is straightforward to address. We have a proposed mitigation there to clarify in the implementation guide that this is permitted. We discussed the specifics of proposed wording with the advisory council in April, and they had good feedback on the wording that we are updating in response to that. We don't think it was actually prohibited to have

different content be released for different permitted purposes, but it is helpful to clarify that explicitly.

Another concern more substantive both in the concern itself and the mitigation, was at one level that the patient would not understand how their information might be used by the app or other system that they are using to facilitate the request and that they may seek to hold the original releasing provider responsible for any mishandling. The proposed mitigation was on a few fronts. We wanted to make sure that any consumer app that is participating in Carequality would have some solid transparency. We decided to rely on the HHS Model Privacy Notice as a means of providing this transparency. The proposed mitigation is that we would make this a requirement formerly in the implementation guide.

On the second piece, we are still working on specific language of how this would be enforced, but ultimately requiring that the consumer apps terms and conditions formally clarify and have the patient acknowledge by using the app, that they are taking responsibility for what happens with their information and that they are not going to consider the Carequality Implementer, to be responsible for what happens once the data has been released in response to the patient request.

***Questions/Discussion**:* Hans asked if the intent would be to provide minimum language to be included that we would like to have in there or do they need to figure it out.

Dave responded that the straw proposal is to develop minimum language and that has not been provided yet. We will see how the council and the Implementer community react to that. One challenge is we could ask for there to be concepts that are represented, but that puts us in the position of interpreting the terms and conditions to say that something addresses the concepts correctly or not. We don't have the final straw proposal draft of the terms yet, but that approach is the intent for now.

We are also planning on updating the Carequality Implementer application process to address anything that is identified as a requirement so that when applying as an Implementer and planning to support the patient request permitted purpose as an initiator, that there would be some additional items in the application to confirm that the transparent privacy notice is based on the MPN and then checking your terms and conditions, probably providing us a link to them where we can verify that the specific proposed terms have been included.

Steven commented that one of the challenges that we face is that the terms and conditions can change from time to time. There is no guarantee that a company will do what it says and the terms and conditions themselves can be incredibly opaque and difficulty for patients to understand. There is a desirability of having some standardized way of representing the specifics, the details, of structuring the terms and conditions in a way that a patient or individual could compare, contrast, and recognize what is in those x pages of text. Have we given any thought to any of that?

Dave responded that the solution would be that if your terms and conditions change, we could talk about how you would craft a requirement that if your terms and conditions substantively change in a way that impacts the way you are presenting the Carequality required language, that you run that by Carequality again.

Leslie commented that in the Model Privacy Notice that we did, we used in the app that HSS developed through this context process and is all written for the patient in plain language and is designed in a way that we know exactly what the terms are of use, what can be sold, where is it

stored, what information is selected and the frequency of that selection. We spent a good deal of time writing that and helping ONC at Healthwise and we used plain language writers to develop it. We know that it is understandable and once the data is removed and the app has been used in Carequality network for communication, if the organization does not live up to the terms and conditions, that is monitored under the Federal Trade Commission. There is some protection there.

Dave asked what is the thought as a reasonable Carequality requirement for changing terms and conditions? For example, you mentioned the terms and conditions and their outcome being reflected in the Model Privacy Notice or in the privacy notice for the app. Is it worth having a requirement that if you update your terms and conditions, you will also update as applicable the privacy notice and get that in front of users?

Leslie affirmed and also noting that in the spectrums of terms and conditions our role is not to judge, but to note that they have been clearly articulated and accepted. Our role is to make sure that anyone who adopts this would have to then be transparent in any changes beyond what is already articulated in the notice. In doing so, we reserve the right to evaluate their participation. If somebody comes up and says we are going to sell your data and going to host this in China and combine this with your DNA data and we will resell this as a health risk assessment across to employers. Well if somebody's agreed to that, they have agreed to that, but that is way beyond, in the current structure. We would then require to be notified that anything out of those bounds would be communicated and that we reserve the right to terminate their participation. If it is transparent and agreed to, we are not judging, but if it is not transparent and is obfuscated in the way that the patient can't agree then we would reserve the right to terminate that relationship.

Dave agreed and we could require that if you update your terms and conditions, that you update your privacy notice and that the privacy notice accurately reflects the actual terms and conditions.

**Next Steps and Proposed Pilot Approach**

- Steps already underway
  – Proposed updates to Implementation Guide are in progress
- Advisory Council has provided feedback on some, others are awaiting legal counsel input
- Updates tentatively planned to be adopted simultaneously with planned updates to incorporate feedback from Document Content Workgroup
  – Implementer application process updates also in process
- Proposed pilot approach
  – In advance of new requirements being formally adopted in the IG, implementers can voluntarily comply with them
  – Such implementers can provide Carequality with evidence of their compliance (e.g. links to appropriate T&C text and privacy notices)
  – Carequality can, in turn, make this evidence available to other implementers, who can use it as an objective criterion on which to base their willingness to honor an implementer’s queries

- This is permitted under non-discrimination rules since these queries use the “Patient Request” permitted purpose
  – If the Committee approves of this conceptually, we will seek advice from counsel on accomplishing these steps in a way that minimizes any risk to Carequality

***Discussion Summary:*** Dave commented that we will continue to refine the precise details for proposed updates to the implementation guide. We are also working on those Implementer application process updates and those are relatively easy to add once we actually know the requirement. The challenge we have is that the implementation guide takes time to update. We are anticipating that there will be updates coming later this year focused on content requirements. Ideally we would like to only have one set of updates that we would do later this year and have that incorporate the patient request related things as well as the content related things. There will be some miscellaneous items identified as well, but have one round of updates and have that happen later this year.

There is a hope that we wouldn't necessarily have to wait until that point to allow organizations to start moving forwards based on the overall recommendations. The thought is that we could have voluntary agreements to comply with the requirements. There is a pre-req that we have to have largely decided what the requirements are going to be and have actual text for all of these things. We are not there yet, but the idea being once we have that set, organizations can voluntarily agree to comply with them. They can provide us with evidence of that compliance and we can make that evidence generally available to the Implementer community, who then can use it as an objective criterion of which to base their willingness to honor an implementer's query.

If that seems reasonable to the committee, we will get Steve's advice on how to do this in a way that minimizes any legal risk, but then go ahead and implement this approach and look to recruit some organizations on the provider side who would be willing to be early adopters and accept these queries from the Implementers who are willing to voluntarily comply with the requirement.

***Questions/Discussion****:* Hans agrees that early adoption would be good and would like to consider how do we generally do that on topics that have matured enough, that are baked enough to have a good sense of general direction that are not yet reflected in, be it the implementation guide, the CCA or other documents, but that there is a comfort level by the implementers.

Dave agreed and commented that we would have three different steps. One would be to review it with the Implementer community, two would be to review it with the advisory council and then, based on their feedback, bring it to this group and have the steering committee review it. The difference is that we would in this case, maybe go through that process and then set it aside while waiting for other things to also go through that process and put them through the official approval process together. If we have gone that far should we just go ahead and make the updates at that point.

Hans commented that it goes to the balance of having multiple items, whether we wait for everything to be ready and published and therefore delay the opportunity to start to adopt. I think we are starting to get more examples of that happening. What's the reasonable way so that it's clear and transparent when people feel comfortable to move?

***Action/Follow up:*** Dave asked if it would be helpful to put out a proposed process for how we would consider something to be sufficient for it to be voluntarily adopted as described here?

Members commented that it would.

Dave will put together a proposal and distribute that to the group and then see where the discussion leads.

*Meeting was adjourned at 1:58pm EST*