Consent Policy Design Group

Meeting Minutes

Meeting Date	Meeting Time	Location
April 23, 2019	1:00PM – 2:00PM	**Join Zoom Meeting:** https://zoom.us/j/269726549 **Dial:** +1 646 876 9923 US **Meeting ID:** 269 726 549

Design Group Members					
Stacy Beck, RN, BSN	x	Susan Israel, MD	x	Nic Scibelli, MSW	
Pat Checko, DrPH	x	Rob Rioux, MA	x		
Carrie Gray, MSIA	x	Rachel Rudnick, JD			
Supporting Leadership					
Allan Hackney, OHS	x	Chris Robinson, CedarBridge	x	Lauri Johnson, HIE Entity	X
Demian Fontanella, OHS	x	Ross Martin, CedarBridge	x	Lisa Moon, Velatura	
Michael Matthews, CedarBridge	x	John Schnyder, HIE Entity	x	Tim Pletcher, Velatura	
Carol Robinson, CedarBridge	x	Sabina Sitaru, HIE Entity	x	Tom Agresta, UConn Health	x

Minutes

	Topic	Responsible Party	Time
1.	**Welcome and Introduction of New Participants**	**Michael Matthews**	**1:00 PM**
	Michael Matthews welcomed the Design Group members and provided an overview of the agenda. Michael introduced members of the CedarBridge support team and welcomed Pat Checko and Stacy Beck, who were not able to attend the kickoff meeting. Michael asked Stacy and Pat to provide their background and share their initial perspectives on consent, and why they are interested in participating on this Design Group. **Pat Checko –** she explained that a lot of her questions and concerns in this space are beginning to be answered, as evidenced by the SHIN-NY White Paper that was distributed. Pat said she is focused on the discussion of confidentiality vs. privacy. Pat said that one of her questions relates to a previous statement that the HIE has the authority to collect all of the data from state agencies, and whether specially protected information, such as confidential data from the Department of Public Health, will be excluded. Pat is wondering what specific authority allows the HIE to collect this information. Ross asked for clarification on which slide referenced this authority. Pat said that she will find the slide in question and frame her question more succinctly. Allan Hackney explained that there is no specific authority. Allan explained that in general the Trust Framework, which is the legal means by which participants would connect to the HIE, is structured in a way that allows participants to sign a use case-specific exhibit that explains how data will be exchanged with other participants that have patients in common, following HIPAA treatment, payment, and healthcare operations rules. It doesn't matter if it is a hospital, physician group, lab, or state agency, as long as they sign a specific use case exhibit, they are allowed to exchange data for the reasons that are specified in the exhibit. Susan Israel asked if the Department of Public Health is in a separate category from other state agencies. Allan explained that this pertains to all agencies. **Stacy Beck –** she said that she echoes Pat's focus on the discussion of confidentiality vs. privacy. She is interested in listening to other's comments and concerns throughout the process.		
2.	**Public Comment**	**Attendees**	**1:10 PM**
	There was no public comment.		
3.	**Review of Consent Design Group Role, Workplan, Schedule, and Desired Outcomes**	**Michael Matthews**	**1:15 PM**

	Michael provided an overview of the Consent Policy Design Group workplan and reviewed the progress that was made during the first discussion. Michael provided an overview of the role of the Consent Policy Design Group and the process that will be utilized to develop recommendation for submission to the Health IT Advisory Council. Michael provided an overview of several level-setting discussion points, including that the patient should be considered the "north star" in all deliberations and that consent policies should be developed in a flexible way to allow for adaptations over time, as the regulatory environment will continue to change. Michael also explained that a consent management solution that gives individuals the ability to manage their consent preferences will need to fit within the workflows of provider organizations as well as meet the needs of consumers and patients.		
4.	**Review of Federal and State Regulatory Landscape**	**Ross Martin**	**1:20 PM**
	Ross Martin introduced the next topic, which included an overview and summary of the content that was discussed during the first Design Group meeting on April 9, 2019. Ross said that consent requires multiple elements of understanding, including policy, technology, and patient engagement. Ross provided a summary of several pending proposed rules at the federal level, including the draft Trusted Exchange Framework and Common Agreement (TEFCA). Ross explained that since the last meeting, the feds released the second draft of the Trusted Exchange Framework (TEF) portion, which included several addendums, such as the minimum required terms and conditions for entities that want to become Qualified Health Information Network (QHIN) participants. The second draft also included the technical framework for a QHIN. Ross explained that the second draft goes deeper in certain areas and expands upon / integrates details from the other federal proposed rules relating to information blocking. Ross explained that TEFCA will have some implications to the HIE strategy in Connecticut that will need to be addressed. Ross provided a summary of some high-level concepts and themes that are included in the federal proposed rules. In general, these rules are trying to get away from specifying requirements for EHRs, and instead are focusing on the movement of data and ensuring that interoperability is possible without any special effort from providers. This should reduce the complexity from a functional standpoint and allow for more standardization. The rules are also focused on the use of standards-based application programming interfaces (APIs). Next, Ross discussed the Office of the National Coordinator for Health IT (ONC) notice of proposed rulemaking (NPRM) regarding consent management and Consent2Share (C2S). C2S is an open source application for data segmentation and consent management. In the ONC's NPRM related to interoperability and information blocking, they stated the need for data segmentation for privacy (DS4P) criteria, specifically on the need to be able to effectively share sensitive data that requires more granular consent. C2S enables data segmentation and consent management for disclosure of several discrete categories of sensitive health data related to several conditions and treatments, such as mental health and substance abuse disorders. Ross explained that these areas are where things get very difficult in terms of appropriate consent management and exchange. Ross explained that the proposed rule wants to use a standard called FHIR Release 3, which is still a trial standard, as opposed to FHIR Release 2. This example speaks to the challenge of utilizing unvalidated standards and the resulting complexity that needs to be addressed. Ross added that if any Design Group members are interested in having more detailed conversations on any specific topic, CedarBridge is willing to support these discussions.		
5.	**Current State of Consent Policies in Connecticut**	**Ross Martin**	**1:30 PM**
	Ross introduced the next section of the discussion, pertaining to the current state of consent policies in Connecticut. Ross provide an initial disclaimer that the materials presented today highlight some of the		

statutes and policies that may have an impact on the design of consent policies that will govern health information exchange under the new HIE entity, however they are not intended to be an exhaustive review of all Connecticut laws that may apply to the design of consent policies for the HIE. The presented examples are intended to inform the Design Group's work by illustrating exceptions and other special cases that will need to be accounted for when building out the exchange and the policies that govern the exchange.

The first example Ross highlighted related to minors, which are individuals under the age of 18 in Connecticut, except under certain instances, such as emancipation. Ross said that this topic is important because there are additional complexities related to consent management for the minor and the parent or guardian. Consent of a minor's parent or guardian is generally required prior to the disclosure of health care information about the minor. In the circumstances when a minor may legally authorize the treatment without parental consent, then only the minor can consent to the release of information. Ross explained that states are handling this issue differently. Ross expanded on the exceptions for parental consent, such as in the case of minors obtaining outpatient mental health treatment. The relevant issue here is that if a provider is treating a minor under this statute, the provider is prohibited from notifying the parent or guardian of the treatment or from disclosing information about the treatment without the minor's consent. Ross explained that this is also true for minors obtaining substance abuse treatment. In this instance, the Commissioner may use or make available to authorized persons information from patient's records for purposes of conducting scientific research, management audits, financial audits or program evaluation, provided such information shall not be utilized in a manner that discloses the patient's name or other identifying information. Ross explained that all of these nuances are important, because they will all need to be considered when creating effective consent management policies. This is a complex and multi-faceted process.

Next, Ross discussed the exceptions for parental consent for minors obtaining treatment for sexually transmitted diseases or venereal diseases. There are additional nuances to this statute, which include the need for the treating physician to report to the Department of Children and Families (DCF) if the minor is under 12 years of age.

Next, Ross explained the statute pertaining to emancipated minors. Emancipated minors must be at least 16 years of age. The effect of emancipation is to release the parent or guardian from all obligations of guardianship and allows the emancipated minor to assume the responsibilities of an adult, including consenting to medical, dental, or psychiatric care.

Pat Checko stated that there is currently a bill proposed in the legislature that allows minors to receive prophylactic treatment for HIV if they have been exposed, and the same consent rules as described above would apply.

Next, Ross explained the commissioner's list, in which a health care provider must report each case occurring in such provider's practice, of any disease on the commissioner's list of reportable diseases, emergency illnesses, and health conditions to the Director of Health of the town, city, or borough in which such case resides, and to the Department of Public Health. Ross provided an overview of the current list of reportable diseases and illnesses, which is an extensive list.

Ross provided an overview of HIE operations and the statute that states that state agencies that participate in the Connecticut HIE, subject to federal restrictions on disclosure or redisclosure of information, may disclose personally identifiable information held in agency databases to the administrator of the HIE and its subcontractors for the purposes of (1) network development and verification, and (2) data integration and aggregation to enable response to network queries. Such

	disclosure must occur in compliance with state and federal laws and the administrator and their subcontractors cannot further disclose personally identifiable information. Ross explained the nuances of consent related to HIV status. No person who obtains confidential HIV-related information may disclose or be compelled to disclose such information, except to a list of specific individuals, and the information cannot be disclosed further. Next, Ross provided an over of the cancer registry, and its relevance to this discussion. Under the statute, the Department of Public Health shall be provided such access to records of any health care provider, as they deem necessary, to perform case finding or other quality improvement audits. Pat Checko asked if we will be recommending changes to the statues to allow for the transfer of information. Allan Hackney said that this is a good question and one that he would be interested in having the Design Group consider as part of their recommendations. Allan said that if the Design Group's view is that there would be a benefit for having this data be available for exchange, he would suggest that the Design Group should draft a recommendation for a legislative change to Connecticut-specific rules to enable this exchange, if the current statute is an inhibitor. Allan said that the statutes will matter for the edge cases, such as behavioral health, substance abuse, etc. Allan would leave this decision up to the Design Group. Pat said that in previous Design Groups, we have discussed this idea and thought that it might be a necessary recommendation.		
6.	**High-level Overview of Policies from Bordering States**	**Ross Martin**	**1:50 PM**
	Ross introduced the next topic, pertaining to consent policies from Connecticut's bordering states as a way to inform our conversation. Ross said that the models vary quite extensively. Across the country, opt-out is the most common as an overall framework. Some states, including some in New England, are more complicated and nuanced. Ross provided an overview of the Statewide Health Information Network for New York (SHIN-NY). A SHIN-NY White Paper was distributed before the meeting, and Ross though this document did an excellent job talking about these issues in a general issue, including the pros and cons of the different models. All of the models have implications and create complex issues to address. One of the fundamental issues, is that if everyone needs to consent to the exchange, it takes a long time to acquire critical mass. In New York, there are seven Qualified Entities (QEs), and their model is unique. They rely on a consent-to-access model, as opposed to a consent-to-disclose model. Under a consent-to-access model, patient information is uploaded by participants to the QE without patient consent under a business associate agreement, however, the data maintained by the QE is generally not available to participants until the patient provides consent authorizing the participant to access the patient's information. There are some exceptions to this model, such as point-to-point exchange between providers with a care relationship for a shared patient. Also, in New York, hospitals and healthcare facilities with certified EHRs are required to participate in SHIN-NY. SHIN-NY has been updating their consent policies recently, and he would encourage members to review the White Paper (pages 9-19) because they do a nice job of explaining their approach. Next, Ross provided an overview of the Mass HIway in Massachusetts, which utilizes a combination opt-in/opt-out model. There is an exception for Direct messaging (secure provider-to-provider email). Ross provided an overview of the opt-in services versus the opt-out services under the Mass HIway model. Next, Ross provided an overview of the Chesapeake Regional Information System for our Patients (CRISP), which utilizes a much more traditional opt-out model. Ross said that he provided links to a number of different consent forms from various organizations. He recommends that Design Group members review the documents to understand how this is discussed at a patient-level. Susan Israel asked if Ross can describe the model that is used in Massachusetts again and how they provide their data to public health or utilize break-the-glass functionality. Ross said that currently, Massachusetts		

	does not have these services available at this time. Michael said that in the interest of time, we will flag this topic as the starting place for the next meeting, as well as Pat Checko's previous question.		
7.	**Wrap up and Meeting Adjournment**	**Allan Hackney**	**2:55 PM**
	Michael provide an overview of the agenda for the next meeting (May 7, 2019). Michael adjourned the meeting and thanked everyone for their time and participation.		

Upcoming Meeting Schedule: May 7, 2019, May 21, 2019; June 4, 2019