OeHI
Office of eHealth Innovation

Meeting Name: Consent Management Working Group
Call In: Zoom Link: https://us02web.zoom.us/j/84144212711 (Panelists, please use your individual links sent to your email)
Location: Virtual Only
Meeting Materials: • January Consent Workgroup Meeting • Contexture Meeting Slides

Meeting Date: 01/19/2024	**Meeting Time**: 10:00am - 12:00pm

Agenda Topic	**Time**
Welcoming Remarks and Introductions **Wes Williams** • Introductions - Allie McGee, Cassi Niedziela, Micah Jones, Lyn Snow, Melissa Kotrys, Abigail Tucker, Alexis Harper, Ashley Darnell, Deanna Towne, Karen Haneke, Erin Crites, Heather Culwell, John Green, Jane Wilson, Justin Man, Mary Beth Haugens, Rick Curtsinger, Stephanie Pugliese, Wes Williams • Wes Williams' tenure as an eHealth Commissioner is ending in 2 weeks	**10:00 -10:05 AM**
Contexture: Sensitive Data Solution:Tagging and Segmentation of Pt 2 Data **Micah Jones/Deanna Towne/Melissa Kotrys** • Micah Jones - VP of Compliance, In-House Counsel • Deanna Towne - Chief Information Officer • Melissa Kotrys - Chief Executive Officer • Contexture is dedicated to addressing 42 CFR Part 2 consent challenges. Working on pioneering solutions that balance compliance with operational efficiency and patient privacy • Sensitive data = data that is protected by 42 CFR Part 2 regulations. Data that comes from mixed use facilities or 42 CFR Part 2 facilities, including non-42 CFR Part 2 data if it comes from a 42 CFR Part 2 facility. -History of Sharing Sensitive Data at Contexture • Nearly a decade of work in this space • Contexture's participants have consistently advocated for timely sharing of health information through the Health Information Exchange(HIE) to support whole person care, care coordination, reduce duplicative treatment, and minimize costly mistakes • Self-funded solution that incorporates community feedback	**10:05 -10:35 AM**

- Platform is in testing, not launched yet
- Want to launch the system with early adopters in the next few months. To be announced soon.
- Opt-Out Model
    - Patients can opt-out of participating in HIE. If they opt out, no health info is accessible to users through the HIE. Contexture's participants must inform Contexture of the opt-out decision.

High-Level Overview

- Before sending data, 42 CFR Part 2 data suppliers must inform Contexture that the data includes sensitive data and sign an appropriate contract
- After the contract is signed, Contexture tags and walls off the sensitive data, based on the data supplier.
    - Ex: Community Mental Health Clinic (CMHC) with a single EHR that co-mingles sensitive data with non-protected data. Contexture walls off all data funneled to the HIE from the EHR. If a provider sends any 42 CFR Part 2 data, all data from the provider is treated as sensitive data.
- 2 Pathways
    - Consent-based
    - Medical emergency-based (break the glass emergency)
- If a patient consents to share 42 CFR Part 2 data, provider uploads consent form → activates consent based access rules for patient data from that provider
- Authorized users can access the patient's data (both sensitive and non sensitive from part 2 providers)

Tagging 42 CFR Part 2 Sensitive Data

- Can receive data through HL7 and encounter and results messages
    - HL7 is the primary method Contexture receives data today
    - HL7 is the universal language to share health information
    - HL7 can vary across healthcare systems, which makes standardization a challenge → challenge for parsing out 42 CFR Part 2 data. No way to distinguish 42 CFR Part 2 and non-42 CFR Part 2 data.
    - EHRs don't regularly distinguish 42 CFR Part 2 data and manage it based on location (like tagging an entire facility or department)
    - HL7 includes broad segments for patient consent (applied to entire patient record instead of specific elements)
- Wes Williams: Are you saying that hospitals that have the most recent HL7 version , you get consent info in the overall package with the CCD?
    - Deanna Towne: referring to HL7 data, not in consolidated care summaries. HL7 segment for patient level consent is received from hospital senders in various segments . Will be requiring all senders to send consent in the same segments
    - Wes Williams: What are you using consent for right now?
        - Deanna Towne: Consent for system level, opt-in, opt-out. Real-time, all the time.
    - Wes Williams: If a provider sends that a patient opts out, do they get pulled from the HIE?
        - Deanna Towne: Yes, they are opted out from the HIE and from sharing data through the portal and several other Contexture products.

- Wes Williams - Are you saying that HL7 feeds you get from providers, some of them send older versions that have no consent info and some send newer versions that do have consent info, but it is not the data element-specific consent in the most recent versions?
  - Deanna Towne - Yes, this segment is a newer version of HL7. Not enough guidance to say you can share specific data elements. Doesn't differentiate at the data element level.
- Wes Williams - For Contexture to do more granular consent you would need a different data feed other than the current HL7?
  - Deanna Towne - No, that's not the intent. Feed would not help. HL7 guidance across the board goes to the message level and applies to the patient, not a data segment level.

Example - CCD Data from Mixed Use Facility

- CMHC employs an addiction medicine specialist. Patient is seen by PCP in a mixed use facility and the physician starts with an encounter summary. If the PCP notices any visible signs of opioid abuse these maybe be noted within the free form notes in addition to other wellness commentary
- Notes are then combined into the overall CCD and passed to the HIE for data sharing
- The issue is that the EHRs are unable to tell the difference between which portion of a patient's summary notes fall within 42 CFR Part 2 regulations and which are general physical or behavioral health notes
- FHIR technology could offer more focus on specific data elements however many facilities and EHR vendors aren't equipped to leverage the technology
- Continuing to work on more granular consent. Hope this workgroup will stay engaged here.
- Wes Williams - If a primary care provider is not a SUD specialist makes a note of opioid use, that's not 42 CFR Part 2 info right? Unless that PCP is part of a specialty facility?
  - Micah Jones - A PCP in a mixed-use facility? That PCP uses the same EHR as the rest of the mixed-use facility, so that data will intermingle with the rest of the data that does include 42 CFR Part 2 data.
  - Melissa Kotrys - Your statement is correct. If that entity decides that their PCP services are not covered under 42 CFR Part 2, they would not generate 42 CFR Part 2 data. In reality, that PCP operates in the same facility as 42 CFR Part 2 providers and that data goes into the EHR. We rely on the entity to tell Contexture if they are 42 CFR Part 2 covered and rely on them to split data out. Some FQHCs have multiple sites and determine that they have only 1 site that offers 42 CFR Part 2 services, and can protect the data from that one facility and not the other sites.
  - Wes Williams - When I see this slide, it seems like the HIE cannot parse sensitive data from free text fields
  - Melissa Kotrys -It differs between different EHRs, facilities and systems as to whether things can be parsed out or not
  - Wes Williams - The reason we are getting into this is because we had a presentation focused on the compliance angle, and we are hoping to get into the technical piece here.

Tagging 42 CFR Part 2 Sensitive Data

- Current State- if providers have any 42 CFR Part 2 data in their EHR and cannot separate with a distinct interface NONE of the data is exchanged through the HIE
- Future State- If a patient consents to share their 42 CFR Part 2 data their data from that provider is accessible to their treating providers in the HIE
- Data from a mixed use facility will be integrated into the EHR system, sent to the HIE along with the consent form allowing treating providers to view it through PC360

Consent-Based Access

- General designation consent form
- Individuals must opt-in to sharing data from sensitive data providers
- Consent form is standardized, and all entities that share data through HIE must use the same consent form. Same rules, builds trust among data suppliers.
- Patients may write in their chosen expiration data for the consent form. Default is 2 years.
    - Action to trigger an expiration is not a current functionality
        - Ex: Someone who needs to go to treatment at a mixed use facility signs a consent form so that consent expires once they get medical treatment.
        - The challenge with this type of consent, particularly for electronic consent, the ADT message will need to include that action and that would need to be sent to the HIE so that access could be revoked or expired at that time.
    - Wes Williams - how did you decide to do all my treatment providers instead of an entity?
        - Micah Jones- these are the 2 types of consent forms that can be used for 42 CFR Part 2 consent. In AZ, they have name recipient consents, but SAMHSA updated rules in 2018 that permitted the use of a general designation consent for all an individual's treatment providers. Long term goal is to support general designation and named recipient consent. First will support general designation because participant feedback favored this. We are not starting with both types because to develop both would require multiple builds.
        - Melissa Kotrys - named recipient consent cannot be supported electronically through HL7. Would require manual intervention. There are multiple layers to this. AZ said there was a large admin burden on providers to do named consent. General designation still gives a patient a choice.
    - Wes Williams - I know that it is legal and compliant. So how do you do it in Arizona with a named recipient?
        - Melissa Kotrys - it's not in the way you are thinking about it. Integrated physical and BH preceded the change to general designation consent. Before general designation consent, you had to share the information as a qualified service organization to the HIE. Before anything could be released, the provider had to ask the patient at the point of care if the patient was ok with the provider accessing your care. When we did that, it was before general designation. It was provider by provider and patients had to consent at each point of care.
        - Wes Williams - So you are saying that before you did it before the general designation it was a lot of work because you had to track

info that came from one provider and had to go to another specific provider, so if the patient was seen by a second provider you couldn't mingle the data?
    - Melissa Kotrys - in AZ we have 50-100 behavioral health providers. All of these are identified as 42 CFR Part 2 protected. Whatever feeds that are coming into the HIE that are designated as 42 CFR Part 2 providers, all the data flows in and is protected and doesn't go anywhere until there is an appropriate consent. Each provider facility must get individual pt consent even if it's the same pt because its based on access to data.BH community is concerned about admin burden on their side.
    - Wes Williams - So it's the consuming provider that needs to get consent in the AZ solution as opposed to the initial rendering provider that's sending it outbound?
    - Melissa Kotrys - we aren't doing that.
    - Wes Williams - When you heard loud and clear from BH providers in Arizona. I was never asked.
    - Melissa Kotrys - yes, specific to Arizona, but we did do a project last year to talk with multiple BH providers in CO to see if there were similar perspectives, and we talked with OeHI about these results. We wanted to make sure that if we went down this road in CO, it would be welcome by providers.

Criteria for Consent-Based Access
- Active general designation consent on file for the patient
- Authorized users must attest they have a relationship with the patient
- User must have a Contexture approved role

Components of Contexture's General Designation Consent
- Very comprehensive
- Includes expiration and revocation rights section
- As required by 42 CFR Part 2 rules, include prohibition on redisclosure notice.
- Signature line for patient or if they are a minor under 13, by the parent or legal guardian

Medical Emergency Access
- "Break the glass" in this context – for accessing sensitive info in the case of a bona fide medical emergency
- Criteria for medical emergency access
    - Disclosure limited to treating providers
    - Necessary for bona fide medical emergency when previous written consent cannot be obtained
    - Individual is unable to consent (not in the event that the are denying consent)
    - Cannot be opted out of the HIE
        - General HIE consent takes precedence over medical emergency

Additional System Features
- Robust auditing compliance and logging
    - Ex: role-based access controls

• Confidentiality in search results
  ○ You can query the HIE and you can see who the data suppliers are. In the case of 42 CFR Part 2 facilities or providers, that can lead to inadvertent disclosures. Names of 42 CFR Part 2 facilities and providers do not appear in search results, only the names of mixed use facilities or non-42 CFR Part 2 facilities.
• Prohibition on Redisclosure
  ○ Language that needs to be attached to all disclosures of sensitive data for consent-based and medical emergency access
  ○ Embedded on all interfaces that display sensitive data and embedded in download, print outs, and exports
  ○ Notice is only displayed when there is sensitive data
• Monitoring and Auditing
  ○ Contexture is deeply committed to transparent system use and regulatory compliance
  ○ Will audit use of the system
  ○ Comprehensive oversight of sensitive data processes including identification storage , consent management, and emergency access
  ○ Auditing consent forms to ensure compliance with 42 CFR Part 2 consent rules
  ○ Auditing medical emergency access
  ○ Logging consent form actions
  ■ Changes to forms, revocation, new form uploaded, etc.
  ■ Will know who is requesting revocations
  ○ Logging of disclosures of medical records
  ○ Will know names of entities to which disclosure was made
  ○ Will notify data supplier within 24 hours that data has been accessed in the case of medical emergency access
  ○ Every intent to safeguard sensitive data and that all access to sensitive data is appropriate	

Discussion and Questions
All
 	
• Jane Wilson - Thank you for this in depth review. At the beginning you explained the difference between 42 CFR Part 2 program data and other types of sensitive data. Can you go back to that?
  ○ Micah Jones - Sensitive data is any data that is subject to protections above and beyond HIPAA. Most common example is SUD data regulated by 42 CFR 42 CFR Part 2. System is currently focused on 42 CFR Part 2 data. Orgs that hold 42 CFR Part 2 data, data is frequently co-mingled with non-42 CFR Part 2 data and there is no easy way to parse it out, so we consider all data from that system to be sensitive data.
  ○ Melissa Kotrys - We have that category of sensitive data so that if there were other types of sensitive data we were receiving that require additional protections that is where we would categorize it
  ○ Jane Wilson - Yes that is where I was going- I wanted to know how you'd share reproductive data or treatments that a minor under the age of 18 are allowed to consent to.
• Wes Williams - if you were going to flag reproductive health data as sensitive data, do you anticipate needing providers to flag that and submit it as such or would you
	10:35 -11:50 AM

endeavor to parse that out?

- Melissa Kotrys - would need to evaluate requirements for any future regulation and have not gone down that road. Have done policy analysis and are tracking developments. Would have the same limitations as we do for SUD data.
- Deanna Towne - Are you asking if we are looking at parsing specific data fields because those would always be considered to be sensitive?
- Wes Williams - I'm hearing that you have a 42 CFR Part 2 repository and a non 42 CFR Part 2 repository right now. Everything that flows into 42 CFR Part 2 repository is shared with ppl who have access to 42 CFR Part 2 repository. When this goes live in CO, all the data that is 42 CFR Part 2 and all of the CCDs, if someone's data is allowed to be shared in that repository then any provider who is allowed to look at it with a treatment relationship to a patient can see all the fields? I'm wondering if you can get away with that approach with reproductive health data or go through the procedure codes because you can't parse it.
- Melissa Kotrys - the challenge we have seen historically for 42 CFR Part 2 is the complexity of the regulation and the hesitancy among community and providers to self-designate what is 42 CFR Part 2 and what isn't and high risk if they get it wrong. We have reverted to the conservative approach of what providers can be comfortable with. In a reproductive health scenario, the community may say you need to exclude all of these diagnosis codes.
- Wes Williams - You can't use technology to determine whether something is sensitive or not, so the general approach of if a provider falls under 42 CFR Part 2 rules, all data falls under 42 CFR Part 2 unless the provider can segment it out into multiple feeds. But there was dissatisfaction with the all or nothing approach. I know CORHIO was able to produce consolidated CCDs from multiple providers and pull it all together so you have demographics, allergies, procedure codes, diagnoses organized. So can't you just send part of it…like just procedure codes but nothing else, or hide allergies? I was hoping that today's presentation would have touched on that.
- Melissa Kotrys - When we consider the solutions we want to offer, we consider the policy and compliance, what is legally possible, the ability to do things as efficiently and electronically as possible, what is allowable and what additional restrictions does the community want. We frame all decisions and solutions among those lines. This led us to the conclusion that starting with general designation consent is meeting community needs at large.
- Deanna Towne - We did build consolidated care summaries into our clinical data repository(CDR). If data that is received is flagged as sensitive, we honor that. We have had conversations about walking through certain segments of data and there is so much risk to take out pieces of clinical data.
- Wes Williams - I hear you saying that data is too messy to be able to segment
- Deanna Towne - messy is not the right word. The structure of interoperable data exchange that is used across the ecosystem of healthcare exchange right now was not structured or built to accommodate for the fact that they would need to be handled differently. We do work very hard with the 2,000

senders that we have to bring the data in and understand what it is and where it should be normalized. Framework is not structured to support a use case like 42 CFR Part 2. Maybe FHIR will have different ways of being able to get data elements but we are not there across the community.
    - Wes Williams - If someone only wanted to send a diagnosis and that's all they've given permission to send, what you are saying is that there may be free text notes coming in as well?
    - Deanna Towne - No, the CCD is where there is free text. What I think you're asking for is for us to be able to go into that diagnosis field and be able to pull out specific diagnosis that would be associated with SUD and fall under a 42 CFR Part 2 designated facility
    - Wes Williams- if a person said the only thing they want to share with a provider is diagnosis and nothing else that would be granular consent. What I'm hearing is that's too messy to do or that we haven't tried it.
    - Deanna Towne- We couldn't only send the diagnosis because you would have to know the patient's identity. I dont think it's as straightforward as that.
- Karen Haneke - It seems that when we are deciding what is HIPAA related and 42 CFR Part 2 related that is being determined by the provider in the case of a facility that provides both types of data.Is that correct?
    - Micah Jones - if a participant wishes to send us data that is sensitive data, they have to tell us that they have sensitive data.That allows us to segment out that data. Most participants have a single EHR. For example a CMHC that offers mixed use services and have a single electronic health record.Even if they were not providing services we would wall off all of that data if we received it
    - Melissa Kotrys - SUD data does not equal 42 CFR Part 2 data. 42 CFR Part 2 data is data that originates from a healthcare provider that provides SUD treatment services and holds themselves out to the community as providing such services and takes federal money. We have to rely on these facilities to tell us they need this definition.

- Lisa Blake (Q&A) - How does this affect the consent under a person at risk of suicide on 72 hour hold, who knows "how to work the system" with what can/can't be shared by who- and who does not have communication in between- and doesn't want to get treatment in mental crisis. When the patient is an adult. Yet family is involved in getting help.
    - Melissa Kotrys - It is the patient in all cases that has to provide the consent for sharing. Can take this as a use case to understand if there are any nuances where a caregiver or part of a journey is allowed.
    - Micah Jones - Medical emergency exception is narrow. Individuals must be unable to give their consent for this access. If a person refuses to give consent, that's not enough to bypass. Consent form is signed by pt, pt's guardian, power of attorney. There are alot of legal protections involved to be able to overrule their right to consent to release of information. We need to spend more time looking at this.

- Allie McGee - I'm hearing a lot about outreach that was done in Arizona. What have you done in terms of outreach in Colorado?
    - Melissa Kotrys - I have some slides that we previously shared with the BHA. In 2022, we conducted a 42 CFR Part 2 analysis to understand if the

environment is similar in Colorado. There was a lot of motivation around whole person care and a desire to have an automated workflow for data. We also work very collaboratively with QHN.
    - Rick Curtsinger- QHN has been sharing 42 CFR Part 2 data for nearly 10 years now on the western slope. We do this based on the facility. We do have SUD data available in the HIE that is not from a 42 CFR Part 2 organization. This is similar to what Contexture is beginning to roll out.

- Stephanie Pugliese - Let's dive in to the chat question about SDoH
- John Green (in chat) - To dovetail on Jane's questions, would you consider any SDOH data to be "sensitive" based on your definition?
    - Melissa Kotrys (in chat) - Hi John - answering in chat and also happy to discuss in the conversation. There are indeed different types of sensitive SDOH data. We handle SDOH data exchange generally outside of the HIE infrastructure today and have a set of consent rules and structures related to our SDOH products and services today.
    - Cassi Niedziela - I agree with John! I'd like to hear more about how this applies to SDoH data.
    - Melissa Kotrys - Every state has different rules. Years ago when Wisconsin came to a summit in Arizona and they mentioned the 100s of regulations that QHN analyzed when developing CRN. General response is that there are segments of SDoH data depending on the topic (DV, types of organizations, etc.). Our systems have a comprehensive consent mechanism in terms of an individuals being comfortable with information being shared with there care team
    - Wes Williams - You noted we are building a separate part that's distinct from the physical healthcare part of the HIE due to different sensitivities. Is there any consideration of breaking things down further and rebuilding healthcare towards some of these requirements that you are seeing?
    - Rick Curtsinger -To participate in a CRN a patient must opt in, this was one of the critical components that we identified as we worked to put together a consent for SDOH data because of the many different opportunities for what social determinants are.
    - Melissa Kotrys - Our intent is to be able to integrate data across healthcare going forward. The way that the CRN system was designed takes a lot of this into account. We're moving in the right direction and driving toward an environment where we can share all that information.

John Greene: This sounds like a good segue into OeHI'S SHIE work. We've done some work on referrals between a healthcare provider and SDOH provider. I know Resultant is conducting discovery sessions and wondered is that the type of things that Resultant will be looking for to inform some of the consent management conversations that we continue to have?

Stephanie Pugliese: Yes we want to learn and build from what's already happening and going well.Consent is very pivotal to the SHIE.

Allie McGee: Are you willing to share any of your consent forms, like the general consent form you mentioned?

Micah Jones: We are still working on getting early adopters and testing on our system. A

demo of the Colorado system isn't ready yet but I'd be happy to share the consent form with you Allie. We can also provide a demo of our Arizona platform. Wes Williams: If Colorado were to build an OeHI funded consent repository that had the granularity that FIHR supports rather than what you're getting in HL7 what would that enable Contexture to do? Similar to Arts question. Arthur Davidson (in chat) - If Contexture continues to deal with all these different versions, yet FHIR might be a more complete solution, how does Contexture see its future integration into the FHIR initiatives being promulgated by ONC through TEFCA? How will the CBOs be supported with this transition to FHIR? Melissa Kotrys: All of our systems are FIHR enabled and are able to handle FIHR today. We are prepared for increasing uses of FHIR standards in the future. What our experience has been is that FIHR is a direction we can go in the future but that healthcare providers are not testing for it and implementing it. It is an area of interest we are open to exploring. I think it's great you want to focus on the impacts of existing infrastructure that are out there. As you think about a centralized repository. I encourage you to think about the different EHR systems you'll be connected to.	
Public Comment & Q&A **Wes Williams, Allie McGee** Lisa Blake - If there's multiple platforms then would it be helpful to see what they are doing well and chuck what's obsolete and redefine what's new. Strengths, weaknesses, opportunities, and threats (SWOT analysis) are a model that's used to simplify and identify when having so much coming together. QuickThought.	**11:50 -11:55 AM**
Closing Remarks **Wes Williams, Allie McGee** Wes Williams: I'd like to conclude today's meeting for the consent workgroup. It's been a pleasure	**11:55 -12:00 PM**

Follow Up:	**Complete By:**	**Responsible:**
Melissa Kotrys to share results from CO provider feedback about consent preferences		
Deanna Towne to provide HL7 segments and where this data could live?		

Contexture team to follow up on FHIR specifics		
Contexture to send current consent forms		