OeHI
Office of eHealth Innovation

Meeting Name: Consent Management Workgroup
Call In: Zoom Link: https://us02web.zoom.us/j/84144212711 (Panelists, please use your individual links sent to your email)
Meeting Materials: ● [Presentation Slides]() ● [Meeting Recording]()

Meeting Date: 9/19/25	**Meeting Time**: 10:00am-11:15am

Agenda Topic	Time
Workgroup Introductions *Allie McGee* **Attendees: Liz Crane, Breck Frye, Evelyn Gallego, John Green, Alexis Harper, Karen Haneke, Amin Kamranfar, Ed Kako, Roberta Lopez, Nancy Lush, Allie McGee, Savanah Mueller, Stephanie Pugliese, Hanni Raley, Alex Reed, Mark Wholey, Jane Wilson** **Allie McGee:** Good morning, everyone. Thank you for coming to this month's Consent Management Workgroup meeting. My name is Allie McGee, Project Manager over the Consent Management Initiative at OeHI, and for the purposes of this workgroup, the Consent Repository Feasibility Study. Great to see everyone this month.	5 mins
[Consent Form Standardization and Digitization]() *Ed Kako, Mission Analytics & Savanah Mueller, EMI Advisors* **Ed Kako:** Welcome, everybody. Today we'll discuss the final new report. We will meet again to review our synthesis and present what will ultimately become the final feasibility report. But this is the last time we'll gather to discuss a new phase of the	35 mins

work. This phase is about standardization and digitization of consent to release.

As I indicated earlier, we'll be talking about release forms, standardization, and digitization. This is a collaboration between the Mission team and our partners at EMI and Patient Centric Solutions (PCS). At one point I will hand slides over to Savanah.

The goals and outline for today's meeting include:

- Identifying challenges with current release form practices.
- Reviewing, in broad terms, what it would mean for consent to have a modular framework.
- Exploring options for workflow and governance.
- Considering possible next steps.
- Opening it up for group discussion.

Current challenges in the system are likely familiar to most of you. There is still heavy reliance on paper and PDF forms across providers. Even PDF forms are not always better than paper. For example, to opt out of Contexture, the state's health information exchange (HIE), you must download a PDF from their website, fill it out by hand, and mail it to a postal address. Fax machines are still used.

This can place a burden on providers. Multiple consents are required for each exchange. It can create barriers for patients who must repeatedly sign consent forms, even within the same system. For example, moving from one Orthopedist to another may require new forms. This can burden the patient experience. Forms often include complex legalistic language, are not always provided in a patient's native language, and can present accessibility issues whether on paper or digital.

The most serious problem for this project is that the forms are not reusable or computable. They are not built of components that could be reused across different instances of consent or frameworks. They are not computable, meaning they do not capture structured information that could be applied in a decision engine to determine in real time who may see information, under what purposes, and for how long.

There are also challenges with identity management and authentication. At present, identity is usually verified by showing an ID in person, or repeatedly logging into a portal with username and password, which is not very secure. More sophisticated consent systems should improve this.

Our methodology included interviewing three people specifically about digitization and standardization:

- Rachel Entrican, Legal Division Director at the Colorado Department of Healthcare Policy and Financing (HCPF).
- Andrea Jones, Deputy Director of Policy and Legislative Affairs at the Colorado Behavioral Health Administration (BHA).
- Dr. Alex Reed, Director of Behavioral Science Education at Colorado University (CU) Medical School.

We also drew on previous interviews to identify friction points and frame questions.

The environmental scan considered interoperability and data standards such as HL7 (Health Level Seven International), FHIR (Fast Healthcare Interoperability Resources), United States Core Data for Interoperability (USCDI), and Centers for Medicare and Medicaid ServicesCMS Data Element Library, but only in the background. These are addressed elsewhere. This report focuses on what is new.

The framework draws significantly from work on modularity developed by the Stewards of Change Institute (SOCI). We focused more on SOCI's work than on data standards, though any system would need to be based on data standards.

What does it mean for consent to be modular? Consent is structured as building blocks: purpose, data type, timeframe, redisclosure, and so forth. There would be a reusable library of core modules, as well as domain-specific modules such as behavioral health, minors, research, social determinants of health, and justice.

When building a consent form, ideally a privacy officer or administrator would log into a form builder and drag and drop the elements they want to include. Colorado-specific modules could be included. A strong advantage of modularity is that it can be forward-looking. For example, if Colorado wanted individuals to be able to consent to share substance use disorder information with 988 linked to their phone number, a module could be created to capture that preference even before the technical infrastructure exists. That way, the technical components can be built later without going back to patients for consent again.

Now, I'll hand it to Savannah to walk through visuals developed by the EMI PCS team.

Savanah Mueller: Thank you, Ed. Continuing with the building block idea, the modular consent concept uses a template-driven method for composing and using consent forms. The method normalizes consents and makes them uniform. There are general guidelines for what components must be included. Within each component or module, there may be various templates to choose from. Not all components are required for every consent form, and organizations administering consents may customize.

Think of the modules as different colors of blocks. A consent could include six colors, but you get to choose which block fits each color. The examples shown today are not exhaustive. Some consents may not need all six blocks.

I want to emphasize that a standardized consent form does not mean a single form to rule them all. It means the underlying structure can be computable and exchanged. It balances customization with standardization.

Ed Kako: To provide further clarification, when we use the word "template" here, we do not mean a completed consent form. We mean one of these building blocks that the form builder drags into the form space, which then outputs a consent form.

Savanah Mueller: Yes, correct. The modules are the high-level areas required in a consent form. The templates are the specific building blocks that fulfill the modules.

Once the consent form is built with the chosen templates, a privacy officer could view the final draft. Details vary by organization, but the form could show each section with relevant options. Ideally, demographics would prepopulate using identity and authentication. Other sections could include checkboxes, dropdowns, fill-in-the-blank, or search functions. For example, "who has access" could include searching a provider directory. Consent duration might default to one year or allow entry of a specific date.

This brings us to the point where we want your input. Which section of a consent form requires the most flexibility or variety of choices? In other words, of the modules we listed, which ones require many different templates for different use cases?

Ed Kako: Another way of framing Savannah's question is to ask: what additional building blocks might be needed, and what options should exist within each? For example, within the patient education and release component, what belongs there, and how should it connect to the type of information being released?

John Green: Could you clarify "who has access"? Does it refer to specific individuals or roles within an organization, or does it mean all organizations across the ecosystem?

Savanah Mueller: Great question. That would need to be defined by a governance group. Options could include: this entire organization has access, only a specific provider, only a care team member, or if they're listed on my care team. The form could also allow distinctions like: my primary care provider may see all records, but my Orthopedist may not see behavioral health records.

John Green: Thank you. Based on that, I'd say "who has access" needs to be very flexible. Roles and organizations change, and patients may need nuanced control.

Nancy Lush: To add, "who has access" could be as broad as any treating physician, or more limited. Organizations must decide what options they want to provide and what they are able to support.

Alex Reed: Looking at the modules list, I think patient education should be a starting point. It frames the whole process: why consent is needed, what information is being shared, and who may access it. There could also be a way for patients to indicate comfort level. For example, on a scale of 1 to 10, how comfortable are you with sharing with a family member, a friend, or your Primary Care Physician (PCP)? That could prompt a conversation if a provider sees the patient is uncomfortable with certain sharing.

Savanah Mueller: Thank you, Alex.

Roberta Lopez: One point I'd raise is consent duration. Often, consent is event-driven rather than date-driven. For example, "as long as this person is enrolled in this program." There's no automatic end date, which creates challenges for tracking and retracting consent. Another concern is revocation. How do we ensure the correct consent is being revoked? And what happens if an agency prints a hard copy and never receives the revocation notice?

Ed Kako: Revocation is difficult. We want individuals to revoke consent if they choose, but revocation almost never deletes all information already shared. If data was pulled into a certified electronic health record (EHR), it can't be retrieved. Patients must understand that revocation stops future sharing but does not erase past sharing.

Allie McGee: On Roberta's point, at the Colorado Social Health Information Exchange (CoSHIE) we developed both a consent form and a required frequently asked questions (FAQ) sheet. Patients must acknowledge receiving it. The FAQ explains in plain, friendly language that revocation stops new sharing from the date of revocation but cannot undo sharing already completed. I'm also working on graphics to illustrate this clearly. Patients need to understand this up front.

Ed Kako: The next topic is identity management. There is a critical link between identity and consent. Granting consent inherently requires verifying identity. You can think of identity management as its own module that must integrate into the larger consent framework.

Fortunately, Colorado would not need to reinvent the wheel. Robust, commercially available identity management and verification systems exist. We do not endorse any specific one, but examples include ID.me, OneCosmos, and Clear. These could be layered into a Colorado system.

Available options include multi-factor authentication, ID scans at point of care, and provider attestation in office. For example, multi-factor authentication could use facial recognition — the same way many of us unlock our phones. ID scans or provider attestation also work; I've had providers or pharmacists recognize me personally and confirm my identity. That's a robust method, but not one we can consistently depend on.

Ultimately, Colorado's system should balance security with usability. Username and password logins are simple but insecure. An insecure system collecting sensitive information is vulnerable to breaches, which would erode trust. Some friction may be necessary, such as two-factor authentication codes or authenticator apps. These steps may annoy patients but are worth it to protect protected health information (PHI). No system is breach-proof, but Colorado can use familiar, usable methods while maintaining strong security.

Any questions?

Ryan Blair (chat question): Are there national conversations about general data protection regulation (GDPR)-style "delete my health data" rights?

Ed Kako: I'll defer to EMI colleagues, but I suspect not much progress has been made nationally.

Nancy Lush: The issue does come up in international privacy and identity discussions. In health care, however, computable consents are not yet widespread, so we're not at that stage. Today, if an electronic medical record (EMR) has your data, you can request deletion, but it's not automated. This conversation will grow as consent systems evolve.

Alexis Harper: I also want to ask about multi-factor authentication (MFA) as a barrier. What about users without smartphones? This could especially impact populations we've discussed in prior meetings, such as justice-involved individuals, who may face restrictions on electronic devices or internet access.

Ed Kako: Good point. Many MFA methods assume access to a phone. There are other ways, but they often require in-office presence, such as facial recognition or fingerprint scans. These may not be realistic in all cases.

Nancy Lush: To add, MFA does not always require a phone. Email, for example, could serve. For regions where phone access is limited, we should enable alternative methods. This will be important for final recommendations and implementation.

Karen Haneke (chat comment): The MyColorado app should be considered as an identity management option.

Ed Kako: Yes, we mention the MyColorado app in the report as a possible identity verification tool. Currently, it centralizes documents like state IDs or driver's licenses. It does not yet function as a full identity management system, but Colorado could invest in upgrades. Alternatively, we could adopt an existing tool. It would be a trade-off between building up MyColorado and procuring an existing system.

Thank you all. So the question for us is: which identity verification methods are realistic for Colorado's population? Options must account for people without smartphones, those with limited internet access, or special populations like justice-involved individuals.

Ed Kako: The final topic is governance and stewardship. Once established that consent would be modular — with building blocks and options — we would need a governance structure to manage it.

Governance must include cross-sector collaboration: providers, legal experts, technologists, patient advocates, and others. Together, they would:

- Define core elements and domain-specific modules.
- Develop plain-language and multilingual templates.
- Propose new modules based on field input.
- Manage updates and modifications.

Stewardship is about ownership. Who is responsible for the modular consent system? Who decides when to add modules or update templates? It could be the Colorado Office of eHealth Innovation (OeHI) or another state agency, but the steward must make sense for the work being done. Governance is a prerequisite before moving further with modular consent.

So the question is: how should governance be structured in Colorado for modular consent to work?

Jane Wilson: When you reviewed other states like Michigan and Connecticut, who was responsible for stewardship? And are there advantages to having the steward be an entity that is not a Health Insurance Portability and Accountability Act (HIPAA)-covered entity?

Ed Kako: Why do you think that might be an advantage?

Jane Wilson: Because HIPAA-covered entities need Business Associate Agreements with vendors. Finding vendors willing to sign those agreements can be challenging. If stewardship were held by a non-covered entity, it could simplify vendor relationships.

Ed Kako: That may be inevitable regardless. As for other states: they have governance structures, but none have built consent in a modular way. This approach is new and cutting-edge. Colorado would be among the first to attempt it.

Mark Wholey: To add, I think we should look to other governance models. The Stewards of Change group, which advanced this concept, is also active in HL7. HL7 has a well-established governance process for standards development, which could serve as a model here. That process manages proposals, development, and release of new frameworks. Colorado could adapt a similar structure for modular consent.

Ed Kako: Thank you, Mark. That’s helpful.

As we wrap up, Colorado must consider both provider-level and patient-level impacts. For providers, modular consent could minimize burden, allow integration with EHRs, and emulate familiar tools like DocuSign. But state support, or even mandates, may be needed to ensure adoption. Connecticut, for example, required commercial vendors to integrate with its HIE, with funding support.

For patients, forms must be in plain language, available in multiple languages, mobile-friendly, and built with universal design principles. This ensures accessibility for people with disabilities, for those using screen readers or other assistive technology, and for diverse populations.

Roberta Lopez: Yes, and through your accessibility, piloting or review would be the ease of translating the words into audio for individuals who need audio support.

Ed Kako: Yes, exactly. That goes back to my point about universal design and individuals who need screen readers. **Allie McGee:** And we should involve community members in reviewing modules and forms. We need to confirm that materials are understandable for ordinary users, not just professionals. **Ed Kako:** Exactly. Governance should include patient advocates and require piloting. During pilots, we can gather user feedback on pain points and confusion, then make modifications. **Ed Kako:** Okay, so we are wrapping up, and very briefly, we wanted to offer some next steps to consider. This is not meant to be directive, but these are next steps that Colorado could consider. To wrap up, Colorado could consider piloting medical and behavioral health modules first. After piloting and refining those, the system could expand to domains such as justice, minors, social determinants of health, and guardianship. The Mental Health Practice Act would also be important to incorporate. It is important to continue gathering feedback from providers, patients, families, and community members. The governance structure itself would also provide feedback and oversee improvements. Collecting useful feedback requires intentional design so that it informs modifications as the system grows. At each step, governance and stewardship would need to remain solid and consistent. The governance body is there to systematize development, manage updates, and communicate with the community. Without it, there would be chaos. With it, modular consent can become user-friendly, person-centered, and responsive to stakeholders.	
Workgroup Questions and Discussion *Mission Analytics & Allie McGee* *Note: Questions and Discussion were incorporated throughout the presentation	25 mins
Public Comment and Closing	5 mins

Allie McGee **Allie McGee:** This is our last topic report for the larger feasibility report. Next month's meeting will bring everything together into a draft synthesis report. We will send the draft version of this topic report to you today or early Monday morning. You will have two weeks to provide feedback. Please pay special attention to identity management options and which modules need further development. Add your comments directly in the Google Doc, as we will use them when presenting to the legislature. Thank you all for your engagement. We look forward to your feedback and to seeing you at next month's meeting. Have a great weekend.	

Follow Up: Provide Feedback on Form Standardization and Digitization Report	**Complete By:** EOB Tuesday, October 7	**Responsible:** Workgroup Members