

Electronic Consent Management (ECM)

What is electronic consent management and how is Washington State using it?

Electronic consent management (ECM) is a cloud-based software solution which will house consents to share sensitive data (e.g. substance use disorder, research, sexually transmitted infection data). It is not intended to store HIPAA general consents for treatment. ECM will be free to use and is meant to replace paper-based consents or integrate with current electronic consent practices by enabling data exchange that will be compliant with 42 CFR Part 2 and other relevant statutes

Why is HCA addressing consent for substance use disorder (SUD) data exchange first?

Efficient data exchange is critical to address the opioid epidemic. Due to this urgency, consents to allow SUD data exchange will be the first type stored when the system is deployed. Other types of consents will be addressed later in the project.

Washingtonians with SUDs, mental health conditions, and other sensitive conditions need their health information to be exchanged securely among a diverse care team in a manner with which they can understand and participate. Eventually, the system is intended to be a general consent solution to enable patient-authorized exchange of various types of data.

When will these changes take place?

HCA plans for the ECM system to be live in May 2024. Until then, providers will continue their current practices.

How is ECM funded?

ECM uses both federal and state funding. It is a component of the Washington State Medicaid system infrastructure.

Is using the ECM system mandatory?

Use of the ECM system is not mandated by HCA or the State of Washington. It will be a resource for providers and Apple Health (Medicaid) beneficiaries to handle consents more efficiently.

Will there be any cost to providers to use the consent system?

There will be no cost for providers to manage consents for their clients using this system. HCA will hold the license with the solution vendor and offer the consent service to organizations serving Apple Health clients.

What types of organizations can use this consent system?

For the baseline solution, only providers that are HIPAA covered entities (CE) may utilize the system. With later expansion, other non-covered entities such as social services agencies could use the system with role-based access.

Can clients use the system themselves or only with their providers?

Initially, only providers will use the system. In the future, HCA will likely add the ability for clients to manage their own consents in addition to providers.

What is HCA doing to ensure the system is secure?

HCA will require the consent system vendor to comply with all state, federal, and industry-standard security protocols and laws. The system must complete a thorough security design review by the Office of Cyber Security within the State Office of the Chief Information Officer (OCIO).

It will also undergo a complete certification process by the Centers for Medicare and Medicaid Services (CMS). This includes verification that the application meets all federal security requirements.

Will the new consent system exchange the data or only manage consent?

This solution will only manage the consents. Providers will continue their current processes to exchange data such as fax, secure email, US mail, and direct data exchange. Later, there may be integration with other IT systems to trigger data exchange once the consent is active.

Is HCA talking with other states about their similar ECM solutions?

Yes, HCA is currently and has previously had peer-to-peer conversations with other states, including but not limited to Alaska and Arizona.

Is this solution going to follow the ONC standards and guidelines developed with SAMHSA?

Yes, HCA will follow SAMHSA's substance abuse confidentiality regulations as well as the Office of the National Coordinator for Health Information Technology <u>Trusted Exchange Framework</u> and <u>Common Agreement</u>.

Is HCA aware of the proposed changes for 42 CFR Part 2 published in the November 2022 notice of proposed rulemaking (NPRM)?

Yes, HCA is aware of the NPRM and submitted formal comments from the agency to CMS.

Has HCA selected the vendor for the ECM solution?

HCA has announced CodeSmart/Midato Health as the successful bidder (ASB) for the ECM solution.

Will the consents be blanket consents, or will they be on a provider-to-provider basis?

42 CFR Part 2 allows for a general designation whereby information can be shared via a health information exchange (HIE) for all past, present, and future treating providers and that will be explored as the system is deployed. HCA can add more granular provider-to-provider consents at a later date based on future use cases and user need.

Will each organization or provider have to build a new EHR or HIE interface for this system? If so, who will pay this cost?

HCA will be working with the electronic consent solution vendor and EHR vendors to create the interface. This is vendor based rather than the responsibility of individual organizations or providers.

This cost is part of HCA's contract with the solution vendor. Unique situations can be discussed with HCA directly, as well as additional functionality that may not be addressed in the baseline solution.

Is HCA mitigating barriers for marginalized populations when it comes to this solution?

HCA is working closely with stakeholders to identify consent barriers and to mitigate them with the ECM solution. The overall goal is to facilitate timely and efficient data exchange to foster whole person care, especially for marginalized populations.

Will the solution "sit on top" of or integrate into the provider EHR system?

The solution is planned to be interoperable with EHR systems in a later phase of the project.

Will the consents be in multiple languages?

HCA's baseline solution will be in English only, but in the expanded solution HCA plans to add additional languages (likely Spanish, Korean, and Russian). If there are other languages you would like to recommend, please contact us.

Will interstate access to consents be available?

Medicaid clients being seen by providers in bordering states can be included in the initial roll out.

How user friendly is the interface, for clinics and/or potentially for clients?

The vendor has designed a simple to use web portal with all required elements to create a complete consent.

What does the consent form look like?

We are working with our vendor to design and showcase this form at a future quarterly call.

How do I access the ECM? Do users have to log into a separate portal to use the system or can they access it through their existing EHR?

For the Baseline Solution, most users will need to sign into a separate web portal to log into the ECM.

However, if EHRs are interoperable with the electronic consent management system, providers could access the system through their existing EHR utilizing single sign on. For the Baseline Solution, HCA intends to work with one provider and their EHR vendor on an interoperability pilot. Additional providers can access via their EHR during the Expanded Solution deployment in a later phase of the project, assuming their vendor is able to accommodate this work.

Will it accommodate any consent form/consent?

The first use case will be SUD consents only. However, we do intend to add additional types of consents in the future.

Do consents get auto-deleted after they expire?

Consents will be deactivated after they expire. Retention policies will follow applicable state and federal law.

How do I sign up to use the system?

If you are interested in using the system, contact HCA at econsent@hca.wa.gov.