RFI No. 2021HCA10

AMENDMENT NO. 2

Electronic Consent Management Solution

Date Issued: 4/28/2021

To: RFI Respondents

From: **Earl Payne**, RFI Coordinator

Purpose: Post Answers to Questions Received

This amendment hereby modifies and is attached to RFI No. 2021HCA10. All other terms, conditions, and specifications remain unchanged.

The above referenced solicitation is amended as follows: **Response to RFI Questions Received**

Question 1. Will the Consent Management Solution be part of an existing platform, or standalone?

Answer The intent is to utilize a cloud-based commercial product for the core electronic consent component. The solution will be hosted on the OneHealthPort statewide HIE platform and will leverage the state-wide Clinical Data Repository (CDR).

The consent solution will align with the overall strategy HCA has been developing with OneHealthPort. In addition to providing assistance on a consent management solution, HCA is working with OneHealthPort on a broader architecture for consumer-facing services. By expanding the Specialized Services, additional services can be implemented on the same technology stack, thus promoting the ability to leverage existing investments and reducing redundancies in commodity platform capabilities.

Question 2. Will the requested solution need to capture any data along with capturing consent?

Answer The intent is to capture mandated data for compliance with applicable state and federal law, along with inclusion of required disclaimer statements. An example of what the data elements to be captured would include is illustrated on pages 58-62 of the *Sharing Substance Use Disorder Information: A Guide for Washington State* document, published by HCA in 2019. This document can be found on the HCA web site: https://www.hca.wa.gov/billers-providers-partners/programs-and-services/substance-use-disorder-sud-consent-management

HCA does not intend to capture other clinical or administrative data as part of this system beyond what is required to complete creation, modification, revocation and tracking of consent. In the initial iteration of the solution, the actual data exchange will be completed outside the system by the providers using their current processes.

Future iterations of the consent management solution will route sensitive information to accomplish the actual data exchange. As the system is built out, consent information will be sent to a data repository that will Integrate with the external consent management solution to enforce consent (e.g. the statewide Clinical Data Repository sponsored by HCA), where individuals/organizations will be able to view the data via a Clinical Portal or query to view data in their native EHR or other system. The statewide Clinical Data Repository is currently live and contains data for Medicaid Managed Care enrollees. Other client populations will be added to the CDR in the future.

Question 3. Could you provide a comprehensive list of homegrown and off-the-shelf systems that the solution will need to integrate with?

Answer The list of "homegrown" systems should not be relevant if the consent management solution integrates with other applications in a loosely coupled fashion. More specifically, this means that the consent management solution must support the collection and retrieval of consent via APIs. The primary type of system that will leverage a consent management will be a clinical data repository, though others will leverage it in the future via custom application workflows for clinical data processing as well as consumer-facing mobile and web applications.

Question 4. Does the Health Care Authority have a standard process to capture consent now? Where and how is that data stored?

Answer HCA does not have a standard process to capture consent now. The consent management process is currently handled by the providers.

Question 5. Section 2. Background, page 7: Could you provide a sample or samples of the consumer facing applications referenced in this section.

Answer Consumer facing applications could include Advance Directives, behavioral health and other clinical assessments, SDOH assessments, and others. HCA has not defined those

items and compiled specific requirements at this time; however, we would expect that they would be very similar to those currently utilized by provider organizations.

Question 6. What output does the Health Care Authority seek to have after capturing consent? For instance, is the agency expecting an audit trail, or a completed form/document?

Answer This solution will provide a single "source of truth" repository for a master electronic consent for a client. The required data elements and other verbiage included in the consent would be standard and would be kept compliant with updated federal and state laws, especially 42 CFR Part 2. This will reduce the number of incomplete, noncompliant and redundant consents. The consent system would be deployed initially as a Baseline Solution with basic functionality to handle creation, modification, revocation and tracking of consents. The solution would then be built onto incrementally to expand functionality and address additional use cases. Uploads of scanned paper consents is not planned in the electronic consent management solution.

There would be an audit trail for all access and activity within the system.

Question 7. At what point or points in the consent process would eSignature capabilities be required?

Answer Electronic consent would be required at consent creation, modification and revocation. The system should also capture electronic signature of a witness/secondary party (i.e. agency staff) when patient consent is created, modified, or revoked.

Question 8. Section 1. RFI Goals and Objectives, page 3: When does the federal funding from the Medicaid PARTNERSHIP Act expire?

Answer HCA is currently securing new funding for procurement and deployment of the electronic consent management solution. The Medicaid PARTNERSHIP Act funding has expired.

Question 9. Is this a new requirement, or is there a vendor providing these services? If so, what is the vendor name, their contract term, and the value of the contract?

Answer This is a new system that HCA is deploying. There are no current vendor contracts for electronic consent management.

Question 10. What is the estimated budget for this project?

Answer HCA is still working to finalize the project budget. Cost information submitted as part of this RFI could assist the agency in that process (per Section 1.1 of the RFI).

Guide – The Health Care Authority plans to use this RFI to promote speed to value in our effort to design, procure, and implement the Electronic Consent Management solution in the following ways:

- *Consider additional system functionality available in the marketplace*
- *Gain additional cost information to finalize the project budget*
- *Create an RFP distribution list (anticipated in 2021)*

Question 11. Is there a timeline for a formal solicitation to be reached?

Answer HCA is planning to release a Request For Proposal (RFP) later in 2021.

Question	RFI Section	RFI Page #	Question/Comment
12	Exhibit A, System Requirements, Baseline Requirements, 1. Technical, Question K	12	Please provide clarification in regards to "portability of the products data."
13	Exhibit A, System Requirements, Baseline Requirements, 4. Consent Creation, Question A	13	Given that current 42 CFR Part 2 rules allow a client to specify different disclosure parameters for different providers, different purposes, and different kinds of information, it is likely that there is a need for multiple consents to be active for the same client. Since requirement 4a requires that there is only one active consent, is it meant to be applicable for all (i.e., past, present, future) treating providers with the same purpose and kind of information?

12 Answer Portability of the data means that the policy and consent records (i.e., the data) must be exportable from the consent management solution for use outside of it in a standards-based interoperable fashion. Examples of standards would be FHIR or BPPC/APPC. An interoperable fashion would be through web services, for example.

13 Answer There will be one active master consent that is meant to be applicable for all (i.e., past, present, future) treating providers for all purposes and kinds of client information.

As the system is built out, it can then also manage one (1) or more granular release of information components associated with the one (1) active master consent per person. Past experience with other organizations attempting to deploy electronic consent solutions has found that starting out with very granular directed consents between specific providers becomes exponentially complex very quickly. And many times this level of granularity is not needed. This system is intended to be deployed with a wider option for data release, and then allow more "point to point" data release in a controlled way for certain use cases.