My Health Hub powered by Aidbox

Executive summary

Problem

We address two related problems in this proposal. First, we provide consumers a way to control access to their EHR data at the application level by FHIR-enabled apps, regardless of the underlying platforms of these different systems. Consumers use a variety of devices, some run Windows, others run Android, some iOS. Their EHR data might be in Epic, Cerner, and Meditech. We solve the patient's problem of managing these multiple connections so that consumers can enjoy a higher level of access to digital health services.

The second problem addressed by this proposal is that healthcare delivery organizations need to support standards-based, secure access to patient data and lack resources for doing this. While this is likely to be a regulatory requirement at some point, it is also an important step towards reducing barriers to digital patient engagement. Evidence is widespread that increased patient engagement is associated with better outcomes. Our proposal saves development expense by health systems and EHR vendors and allows faster adoption of the FHIR® standard.

These potentially transformative forces – empowered consumers, digital health tools, and risk-bearing providers- are all supported by federal regulations intended to open up the proprietary "walled gardens" of most EHR systems. For example, the 2015 Edition (Health IT) Certification Criteria and EHR Incentive Program-Stage 3 set new challenging API requirements for the EHR technology on the vendor and provider sides. In accordance with these new requirements every provider organization should enable patients to access their clinical information with use of third-party applications via an ONC-certified API.

Here is a quote from the EHR Incentive Program-Stage 3:
"... the provider would need to fully enable the API functionality such that any application chosen by a patient would enable the patient to gain access to their individual health information provided that the application is configured to meet the technical specifications of the API. Providers may not prohibit patients from using any application, including third-party applications, which meet the technical specifications of the API, including the security requirements of the API."

And another quote from 2015 Edition (Health IT) Certification Criteria:
"Our intention is to encourage dynamic registration and strongly believe that registration should not be used as a means to block information sharing via APIs. That is, applications should not be required to pre-register (or be approved in advance) with the provider or their Health IT Module developer before being allowed to access the API."

While the goal is clear, a way to achieve it is not. Bringing patients to patient portals was a challenge that many providers struggled with. Enabling patients to manage third-party applications and their access to patients medical data is a much more complex task. Not only does it have to be simple for patients to use, it should also provide patients with confidence that

they will share only a subset of their medical data that they are willing to share. A company that can solve this problem successfully has a great opportunity to offer their solution to the many EHR vendors and provider organizations that will have difficulty answering all the market needs.

Solution - Health Samurai's solution My Health Hub powered by Aidbox

The solution is a patient-facing web application "My Health Hub" (working on mobile and desktop devices) that allows patients to register third-party applications and customize permissions for them to access their medical information via an ONC-certified API leveraging all HEART implementation specifications.

Typical My Health Hub usage scenario

Patient receives credentials for My Health Hub while at the provider organization. He logs into My Health Hub and registers a third-party application that he wants to use and which needs access to some of his medical data.

He chooses what data he wants to share with this application via a selection of pre-defined policies (e.g. "Demographics only", "All lab test results", "All problems except psychiatric" etc). He can immediately see what data will be shared with the application and add/remove policies in accordance with his needs.

Patient logs into a third-party application with use of My Health Hub login (OAuth 2.0). That third-party application receives patient's data from My Health Hub via FHIR API.

Patient can register/de-register as many third-party applications as he wants and he can customize different permissions for them. My Health Health Hub powered by Aidbox receives data from legacy EHRs with use of available connectors.

Methods and Technologies

2015 Edition (Health IT) Certification Criteria doesn't force developers to use standards now but indicates that it will be needed very soon:

"We intend to pursue a standards-based approach for this criterion in the future… We recognize and encourage the work being done to develop emerging standards in this space, including OAuth, OpenID Connect, UMA, and the OpenID Foundation's HEART profile."

But certification of the API is not the final step in the Meaningful Use demonstration. Provider organizations will provide their patients with access to an ONC-certified API that can be used by third-party applications. And it is well known what API the majority of third-party applications will expect. Engagement of patients with their health care has always been a challenge. To overcome this challenge a provider organization needs to have access to the best applications

on the market. It simply can't afford locking itself into a limited set of applications developed for a non-standard API.

My Health Hub will be built on top of a FHIR platform Aidbox, which was developed by Health Samurai, but will allow its deployment on top of FHIR servers from other vendors as well. Aidbox platform already leverages many of the standards that are at the core of the HEART WG implementation specifications: FHIR, OAuth 2.0 and UMA. Health Samurai will also support OpenID Connect in the My Hub Health application.

Financial Overview

The development of My Health Hub will be funded solely by Health Samurai (WaveAccess USA, Inc.) from the revenue that Health Samurai is receiving from licensing aidbox technology and consulting works in the healthcare IT space. The estimated cost of My Health Hub patient facing application is $40,000 US and will take about 2 months by a team of a Product Manager, a Technical Lead, a Sr. Healthcare IT engineer, a QA engineer and a designer.

My Health Hub will leverage Aidbox platform and FHIR solutions that Health Samurai has been developing since 2012. The cost of Aidbox platform development is not disclosed.

In accordance with Certified Health IT Product List from The ONC for HIT there are 3425 EHR products certified with the previous certification edition among which there are 870 complete EHR products. For market size estimates we will consider only complete EHR products.

The ONC estimates for satisfying API requirements from the 2015 Edition (Health IT) Certification Criteria is 900–1200 hours not including relevant security requirements and 1200–1800 hours including relevant security requirements. 1500 hours of development at the average rate of $31 US (Software Engineer average hourly wages) gives the cost of development of $46,500. The proposed solution targets at least $40M market.

Health Samurai will offer My Health Hub as a part of Aidbox platform and as a separate solution. The price of My Health Hub will be competitive but will vary and will depend on Aidbox components packaged for a particular client.

Development Plan and Timeline

Existing Aidbox components that will be used in implementation:

- FHIR API (DSTU2 & STU3, tested in the Argonaut project)
- OAuth 2.0 provider (tested in the Argonaut project)
- Connectors to external systems by means of widespread HL7 v2 messaging, CDA/CCD documents (in development), FHIR REST API and custom processable data channels
- Policy-Based Access Control with User-Managed Access (UMA) implementation
- Security subsystems in particular providing HIPAA-eligible infrastructure
- Completely automated cloud infrastructure that uses AWS

Components to develop:

- OpenID Connect support
- Patient-facing web application “My Health Hub”

Planned milestones:

1. First development sprint will start on Oct, 1st of 2016. By Oct, 1st a starting prioritized backlog for My Health Hub will be completed.
2. The main scenario (the first version of the My Health Hub product) will be completed by Nov, 1st of 2016. My Health Hub will be presented to potential clients, their feedback will be collected continuously and will be used for making improvements. The pilot implementation can be started.
3. The pilot implementation of the product will be completed by Jan, 1st and Health Samurai will start marketing My Health Hub to EHR vendors.

Success Metrics

The success of the pilot will be determined by the ability of patients to use My Health Hub without significant assistance. Proper usability testing will be completed during the pilot implementation.

Health Samurai doesn’t expect a high volume of clients until late 2017-2018. The market should become more favorable to Health Samurai solution with providers moving to stage 3 of “Meaningful Use” demonstration. After that we expect to have tens to hundreds of clients.

Risk Management Plan

My Health Hub will be developed as a part of Aidbox platform development which already has several enterprise customers. Developers of Aidbox comprise an experienced healthcare IT team which has been crafting healthcare IT solutions for the US market since 2004. In particular, Health Samurai has developed a cloud inpatient EHR which was implemented in three hospitals in California. Health Samurai is a part of a larger software development organization WaveAccess that consists of more than 200 developers worldwide. WaveAccess USA, Inc carries $5 mil. liability insurance.

The main risk that is carried by the development of My Health Hub application is a potential cancellation of the EHR incentive program, Stage 3. In accordance with information available from public sources in particular Andy Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services, Open API requirements are not going away. But even if EHR incentive program, Stage 3 is cancelled there will still be significant demand for a product such as this. As we move towards accountable care, it is becoming more obvious to many in the medical community that full access and sharing of clinical information is a required element that enables better outcomes and decrease admissions to acute care facilities. In this case, My Health Hub adoption might go slower but the product will still be in demand by the future market.

Health Samurai will provide a solution with all the technical safeguards required by HIPAA. All PHI at rest and in transit will be encrypted. All PHI will be automatically backed up on a schedule. The application will allow only unique user IDs, it will force using of passwords and automatic logoff after a specified inactivity/idle period of time. All the delivered software will implement mechanisms that record and examine activity in information systems that contain or use PHI. A documented emergency access procedure will be implemented as well.

Physical safeguards will be handled by the infrastructure provider (e.g. AWS) or clients in case if My Health Hub is deployed into clients infrastructure. Administrative safeguards along with organizational requirements and policies will be a responsibility of the clients.

Team

Health Samurai - developers of Aidbox, FHIRbase, FHIR.js and other FHIR projects.

Nikolay Ryzhikov - Health Samurai CTO, a technical leader and evangelist, engineering visionary, a FHIR standard contributor and community activist
Pavel Smirnov - Health Samurai CEO, Pavel is responsible for business development
Mike Lapshin - Sr. Healthcare IT engineer
Andrey Rudenko - Sr. Healthcare IT engineer
Alexandra Pavlyshina - Healthcare IT QA engineer
Oleg Sugatov - UI/UX designer

Advisory - Health Innovation NW (Seattle)

Richard Bloch - Over 30 years of systems and software engineering experience in numerous government, military and healthcare projects. Mr. Bloch serves on the Board of Trustees of the Northwest Kidney Centers. He's also a life-long chronic kidney disease patient, and received a transplant in 2013.

Larry Lee - Healthcare sales and marketing professional with GE Healthcare, Siemens Medical, McKesson/RelayHealth, Wolters Kluwer/UpToDate, Viterion Digital Health.

Thomas Lang, MD - Practicing physician, currently ER, with IM training and practice in past. Most interested in making software easier to use in the 'trenches of healthcare delivery'.

Edmund Butler -Digital health startup founder and a senior advisor to hospitals and health plans. Formerly an EHR product strategist in the US and UK.

Eric Fogel, MS MBA - Serial entrepreneur in the health IT and life sciences sectors. Focused on product management and building solutions that solve problems.

John L. Foy, MD, PhD, is focused primarily on physician-oriented functionality in hospital EHRs. He worked with the NIH Clinical Center and several commercial vendors.