

HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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March 15th, 2019

Comments from PCHAlliance: Federal Register RFI on Interoperability of Medical Devices, Data, and Platforms To Enhance Patient Care

Link: <https://www.federalregister.gov/documents/2019/02/15/2019-02519/request-for-information-action-on-interoperability-of-medical-devices-data-and-platforms-to-enhance>

The goal of this effort is to determine whether a vision of sustained interoperability in the hospital and into the community is feasible and, if so, what it will take to realize it. In addition, this RFI looks to examine how users might leverage the existing tools and processes for implementing this shared future vision. Please address the following in your response.

The below are comments in blue font are aggregated from members and thought leaders of the Personal Connected Health Alliance (PCHAlliance).

(1) What is your vision for addressing interoperability issues between medical devices, data, and platforms? How would this plan to create interoperable systems address your key use cases and pain points?

The Personal Connected Health Alliance (PCHAlliance) aims to make health and wellness an effortless part of daily life. The PCHAlliance, a non-profit organization formed by HIMSS, believes that health is personal and extends beyond healthcare. The Alliance mobilizes a coalition of stakeholders to realize the full potential of personal connected health. PCHAlliance members are a vibrant ecosystem of technology and life sciences industry icons and innovative, early stage companies along with governments, academic institutions, and associations from around the world. To support its vision, the PCHAlliance convenes the global personal connected health community at the annual Connected Health Conference, the premier international event for the exchange of research, evidence, ideas, innovations and opportunities in personal connected health.

For many years now, the Alliance has published and promoted the adoption of the Continua Design Guidelines (CDG). The CDG is recognized globally by the International Telecommunications Union (ITU) as the international standard for safe, secure, and reliable exchange of data to and from personal health devices. PCHAlliance's vision Continua Design Guidelines solution for remote patient monitoring covers 4 chronic diseases and health, wellness and fitness.

To address interoperability between medical devices, data and platforms outside of clinical environment, typically in remote and home environments, PCHAlliance has developed the CDG precisely as the interoperable solution for remote monitoring aligned and harmonized. The CDG, which has implemented the HL7 FHIR specifications, now support integration of personal connected health data from 26 vital signs sensors and 40 health, medical and fitness

devices and services, representing potentially hundreds of different products for telehealth and telemonitoring of chronic diseases, including diabetes, heart failure, hypertension and COPD, as well as health and fitness measures.

(2) Who are the relevant parties and their contributions to your interoperability solution?

The relevant parties whom have contributed to the CDG interoperability solution are composed of leading technology, medical device, healthcare industry thought leaders and service providers. The vision behind the CDG is composed of leading technology organizations, medical device and health care industry thought leaders and service providers. These are: AT&T, A&D, CSIRO, Eli Lilly, Intel, Ipsos, Orange, Philips, Roche Diagnostics, Resmed and Samsung and many more. PCHAlliance's success is evident through the adoption of its CDG by many organizations, countries and through its conformity assessment process and CODE for Health programs (open-source commercial-ready drop-in code). Worldwide adoption of the CDG has been an ongoing priority where PCHAlliance has seen significant progress within Austria, China, Denmark, Catalonia, Finland, India, Norway and Sweden and now within the US where both the FDA and ONC have recognized its core protocols and its guidelines. PCHAlliance will continue to bridge the gap ensuring that its work is clearly understood within the personal connected health communities by working directly with key alliances, such as the Bluetooth SIG, HL7, IHE, CTA, ITU, IEEE, JIC, ISO and IEC. Continua's improvements to each of these organizations standards are making interoperability possible in remotely executed health & wellness.

(3) What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?

The challenge is in achieving the global adoption of scalable interoperability.

PCHAlliance believes that the adoption of the CDGs by governments, industry and health organizations worldwide would solve this problem if fully adopted as the solution for solving interoperability lies within an infrastructure that can scale. To scale means that any organization can openly compete and innovate using an open plug-and-play data standard such as the CDG. This is the only way in overcoming the silos and walled-garden approach we currently have today.

PCHAlliance was pleased to see a step in this direction by the CMS Administrator in her keynote at the HIMSS Global conference on February 14, 2019, who said the following in support of CMS's MyHealthEData initiative focusing on patient access to their healthcare data through Application Programming Interfaces (APIs): "The success of data sharing relies on our ability to standardize on structure and semantics, or common meaning of medical terms. And our rule took a strong step to make this a reality. By identifying the FHIR standard to implement our policies, we are promoting scalable data sharing, not just an individual patient record from

hospital to hospital but a model that supports the flow of information across the entire healthcare system. We encourage industry to align in this direction, because it is coming. Locking information into proprietary data models will soon be a thing of the past.”

During the HIMSS’19 Global Conference two new policy changes related to standards & interoperability were also announced by Seema Verma supporting CMS’s MyHealthEData initiative to improve patient access and advance electronic data exchange and care coordination throughout the healthcare system.

The CDG enables Observation Upload (vital signs data for RPM PGHD) over FHIR. PCHAlliance already has an HL7 FHIR Implementation Guideline (IG), <http://build.fhir.org/ig/HL7/PHD/>, and have been helping HL7 FHIR develop their standard for several years now. FHIR became a part of our CDG 2017 version and, later this year, we will improve on this by referencing the latest FHIR standard and with the new FHIR IG (see link above).

FHIR itself is not an API, it’s a standard for health web platforms that enables sharing of resources in an interoperable fashion. API’s are what organizations make to implement FHIR onto their platforms (so a set of subroutine definitions, protocols, functions, procedures and tools allowing the creation of applications that access the features or data of an operating system, application or service). PCHAlliance, via the CDG, has mapped its definitions, protocols, tools, etc. for implementers so that the API is interoperable between different organizations. FHIR alone does not ensure interoperability so it takes organizations like IHE and Continua who both profile on top of FHIR in order to assure interoperability.

(4) Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable? Please explain why you have reached the conclusion that you have.

PCHAlliance believes that the vision is possible, but only through scalable interoperability discussed above.

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