HITRD RFI Responses, March 15, 2019

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

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RFI: 84 FR 4544, Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

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Thank you for the opportunity to respond to this Request for Information. IHE (Integrating the Healthcare Enterprise) is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE technical profiles communicate with one another better, are easier to implement, and enable care providers to use information more effectively. IHE USA is a not for profit organization founded in 2010 that operates as the national deployment committee of IHE International®.

IHE USA improves our nation's healthcare by promoting the adoption and use of IHE and other world-class standards, tools, and services for interoperability. IHE USA engages all levels of public and private sector participants to test, implement, and use standards-based solutions for all health information needs.

IHE is organized by clinical and operational domains and is supported by industry experts with clinical and operational experience to identify integration and information sharing priorities. Vendors, developers, and users of relevant information systems collaborate through

an open process to develop consensus and standards-based solutions to address them. IHE is composed of a number of technical domains including IT Infrastructure, Patient Care Coordination, Radiology, and Patient Care Devices (PCD). The IHE Patient Care Device domain technical committee along with committee members also active in the Personal Connected Health Alliance (PCHAlliance) were engaged to help develop the response for this RFI. For any further questions, please feel free to contact Amit Trivedi at [redacted].

Response to RFI

(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?

IHE USA's vision is to improve the quality, value, and safety of healthcare by enabling rapid, scalable, and secure access to health information at the point of care. The healthcare industry has expanded its focus beyond the clinical care setting to also consider the importance of personal health and wellness and the need to ensure that interoperability extends throughout the ecosystem. Recent proposed regulations from CMS and the ONC also focus on interoperability as it relates to improving patient access, advancing electronic data exchange, preventing information blocking, and improving care coordination throughout the healthcare system. This vision has also been reflected in the pronouncements of top healthcare officials.

CMS Adminstrator Seema Verma said the following at the HIMSS 2019 Global Conference in February: "…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."

The National Coordinator for Health IT, Dr. Don Rucker, also addressed HIMSS conference attendees and described how healthcare lacks the modernized Application Programming Interfaces (APIs) that could potentially drive a smartphone economy where patients access their health data through apps of their choice.

In an effort to bring about this type of alignment to the industry, IHE International is increasing efforts to foster stronger collaborations between standards and profiling organizations to help accelerate the pace of interoperability specification development and deployment. IHE International and HL7 entered a collaboration named Project Gemini, to focus on specific areas of unmet needs and jointly develop implementable specifications that can be advanced through testing at FHIR and IHE Connectathons. Additionally, the Boards of IHE International and the Personal Connected Health Alliance (PCHAlliance) recently unanimously agreed to promote further collaboration between the work of IHE within the clinical enterprise and the work of PCHAlliance/Continua in the personal connected health space to advance end-to-end interoperability within the healthcare ecosystem.

IHE Patient Care Device technical profiles leverage HL7 Version 2 messaging using standardized nomenclature and co-constraints and content models to send near real-time medical device data to Electronic Medical Records and other systems. Message semantics are based primarily on the internationally recognized ISO/IEEE 11073 nomenclature, due to its comprehensive and thorough treatment of the topic. The nomenclature and essential co-constraints are documented and made available at no cost to facilitate adoption. Furthermore, the same nomenclature and co-constraints are used to support rigorous interoperability demonstrations and testing, such as those hosted at IHE Connectathons and by other testing organizations as well as those facilitated in a year-round manner using the NIST RTMMS and NIST test tools. Relevant information communicated via IHE Patient Care Device profiles include vital sign readings, medication administration, alerts and alarms, medical device identifiers and location as well as other information. This information can be used to help caregivers triage alarms, review relevant data, including waveforms, and document trends in patient care. Additional profiles facilitate the identification and management of medical devices during recalls by automatically providing the Computerized Medical equipment Management System (CMMS) with equipment identifiers (UDI, software version) and location of the affected devices. Please see **Appendix A** for more information on the IHE PCD domain, profiles, and the IHE PCD Technical Framework.

As IHE PCD has traditionally focused on medical devices in the acute care setting, the Continua Design Guidelines (CDG) as developed by the PCHAlliance focuses on personal

health devices. 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 Continua Design Guidelines solution for remote patient monitoring covers 4 chronic diseases and health, wellness and fitness. The CDG, which has implemented the HL7 FHIR specifications, now supports integration of personal connected health data from 26 vital signs sensors and 40 health, medical and fitness devices and services. They represent 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.

As these guidelines and integration profiles are drafted, finalized and then implemented within devices and health IT products, IHE Connectathons serve as a unique venue to conduct peer testing and successfully demonstrate that products are market-ready. The IHE Product Registry is a resource to search for products that have successfully tested at Connectathons and support IHE Profiles. The IHE Connectathons continue to expand in scope each year, and include testing of other world-class standards like HL7 FHIR. The 2020 IHE North American Connectathon will also include testing as it relates to Continua Guidelines. The ability to test interoperability between systems by top health IT vendors and medical device manufacturers is one of the greatest values of the Connectathon, and these new, stronger collaborations will help advance and accelerate interoperability throughout the healthcare system.

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

Relevant parties that participate in IHE profiling and testing work include major medical equipment manufacturers, EHR vendors, professional/industry organizations, federal agencies, healthcare organizations, and sponsoring organizations like the American College of Clinical Engineering (ACCE), the Healthcare Information and Management Systems Society (HIMSS), the Association for the Advancement of Medical Instrumentation, and the Radiological Society of North America. Standards development organizations such as HL7 and IEEE define the underlying message protocol and nomenclature standards, which are

then further profiled by organizations like IHE PCD and PCHAlliance. The US National Institute of Standards and Technology (NIST) has played an essential role by providing the on-line repository Rosetta Terminology Mapping Management System (RTMMS) that makes the terminology and co-constraints available to the vendor and provider communities. NIST also supports IHE and medical device interoperability by developing message conformance test tools that are used at IHE Connectathons to ensure that devices and system can and do actually interoperate.

Leading technology, medical device, healthcare industry thought leaders, and service providers have contributed to the development of the Continua Design Guidelines. 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 and IHE International will continue to raise awareness of their work, and continue to improve collaboration between the personal connected health and clinical engineering communities by working directly with key alliances, such as the Bluetooth SIG, HL7, IHE, CTA, ITU, IEEE, JIC, ISO and IEC.

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

One of the challenges the industry faces is a need for increased awareness and education with regards to the benefits of clinical data interoperability based on open standards. Those benefits are lower integration costs, improved patient safety when integrating heterogeneous devices and systems, and improved abilities for the biomedical research community to integrate real-time medical device data with data from other areas in the hospital in a seamless, safe and effective manner - without the need for expensive middleware solutions.

Tracking, maintaining, and updating the hospitals' inventory of existing equipment is another challenge. Most medical equipment has an effective lifespan of 5-10 years, and can often be used far longer. Hospitals use equipment as long as it is clinically viable. For this reason, many of these legacy devices have little or no inherent networking capabilities. The legacy devices that lack networking capabilities require an intermediary system (often called a

‘gateway’) to gather, format and add patient data before sending it to the EMR or other systems. Additionally, clinical needs will always outweigh other concerns. If a medical device provides better clinical outcomes without interoperability, the hospital will select it over an interoperable device that doesn’t work as well clinically. These issues are being addressed by the Integrating the Healthcare Enterprise – Patient Care Devices (IHE-PCD) community. Members include companies that manufacture these gateways; they provide the connection from legacy equipment to the hospital systems. They do this using the HL7 Version 2 messaging and the ISO/IEEE 11073 Medical Device Communication (MDC) nomenclature.

In addition, medical equipment and device data, such as location, use status, software version, self-test results, etc. typically do not flow seamlessly into a receiving system. The systems that receive and store this information are often designed for processing computer information from an Information Technology perspective as opposed to information generated by medical equipment. There is much more information that needs to be tied to a medical equipment record to comply with safety and regulatory requirements. There are systems that are developed to specifically manage those regulatory requirements called medical equipment Computerized Maintenance Management Systems (CMMS). As CMMS manufactures further understand how IHE PCD interoperability can support their business case, we would expect greater adoption of IHE PCD interoperability to help advance the industry.

The rapid rate of adoption of new IT standards and technology often conflicts with the much more conservative pace of medical equipment development and testing. While new standards are quickly adopted (and abandoned) by IT-focused implementers, medical device manufacturers don’t have that luxury. Between designing for the rigors of direct patient care and the regulatory approval process, it is not unusual for it to take several years and millions of dollars to bring a medical device from design to market. They simply cannot afford to throw that away and start again every time a new communication standard is published. Medical equipment manufacturers are not in a position to simply change to the latest protocol *de jour*, especially when there are also real-time bandwidth and latency requirements to consider with regards to the safe and effective and timely communication of medical device data.

The single largest impediment to implementing this interoperability model at scale is simple, and not technical in nature. Ongoing education and awareness of these efforts are critical in order to accelerate adoption rates of open standards, to increase volunteer engagement in standards and profiling groups, and to foster greater collaboration and coordination within the industry.

(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.

The federal vision is viable through scalable interoperability assuming that the industry can come together in alignment to focus on interoperability throughout the ecosystem. There are challenges to achieving this vision, however, many of the capabilities described in the federal vision already exist from a technology perspective. Integrating the Healthcare Enterprise provides many of those capabilities in the acute care setting, the Personal Connected Healthcare Alliance provides the relevant capabilities in the home setting. The increased collaboration between these two organizations to connect personal connected health with the clinical enterprise is an example of how the industry can bring about the change necessary.

IHE USA strongly believes that this federal vision for medical device, data, and platform interoperability end state can be achieved. Organizations like IHE International and the Personal Connected Health Alliance are actively collaborating to achieve end-to-end interoperability throughout the healthcare ecosystem to improve the quality and efficiency of care delivery and the health and wellness of our population. Both organizations are actively participating to advance the maturity of the FHIR standard through profiling and testing. We encourage further dialogue with IHE and the PCHAlliance to improve understanding as far as what capabilities are available in the market today and how we can create stronger collaborations with policymakers and relevant stakeholders to further drive adoption in the industry. We thank you for the opportunity to comment.

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Appendix A

The IHE Patient Care Device (PCD) domain was formed in 2005 to address the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR, potentially resulting in significant improvements in patient safety and quality of care. In 2006/2007 the first profile was successfully developed, tested in a Connectathon and demonstrated at HIMSS '07, exchanging information from vital signs, physiological monitors, ventilators, infusion pumps, and anesthesia workstations with enterprise applications such as clinical information systems. This enterprise-level integration is actively being extended to point-of-care integration, as well as to new workflow integration needs, such as alert communication management.

IHE PCD is sponsored by the American College of Clinical Engineering (ACCE), the Health Information Management Systems Society (HIMSS) and the Association for the Advancement of Medical Instrumentation.

IHE PCD Profiles

IHE Patient Care Device integration profiles include:

- **[ACM] Alert Communication Management** enables the remote communication of point-of-care medical device alert conditions ensuring the right alert with the right priority to the right individuals with the right content (e.g., evidentiary data). It also supports alarm escalation or confirmation based on dissemination status, such as whether the intended clinician has received and acknowledged the condition.
- **[DEC] Device Enterprise Communication** supports publication of information acquired from point-of-care medical devices to applications such as clinical information systems and electronic health record systems, using a consistent messaging format and device semantic content.
- **[DEC-SPD] Subscribe to Patient Data** provides an optional extension to the DEC profile that supports a filtering mechanism using a publish / subscribe mechanism for applications to negotiate what device data they receive based on a set of client-specified predicates.
- **[IDCO] Implantable Device Cardiac Observation** specifies the creation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations) or messages.
- **[IPEC] Infusion Pump Event Communication** allows an infusion system to send detailed non-alarm information on to allow the tracking and logging of the whole history of an infusion operation.
- **[PIV] Point-of-care Infusion Verification** supports communication of a 5-Rights validated medication delivery / infusion order from a BCMA system to an infusion pump or pump management system, thus "closing the loop." Optionally, the [DEC] profile

may be used to selectively monitor the status of the devices that have been programmed.

- **[POI] Pulse Oximetry Integration** specifies how implementers could use the existing DEC and PCD-01 transaction to exchange pulse oximetry observation sets with clinical information systems. It constrains the existing transaction to better accommodate the content of pulse oximetry measurement observation.
- **[RDQ]Retrospective Data Query** allows for patient specific, user-initiated queries of retrospective data stores of clinical data (i.e., retrospective data) for the purpose of aligning those data under a common time frame with the appropriate resolution to support clinical decision making based on the retrospective data. The RDQ is therefore patient centric and collects data from various sources (via multiple queries) to produce a comprehensive report that is meaningful to a given use case.
- **[RTM] Rosetta Terminology Mapping** establishes a set of tools (Excel spreadsheets & XML files) that map the proprietary semantics communicated by medical devices today to a standard representation using ISO/IEEE 11073 semantics and UCUM units of measurement. Additionally, the Rosetta tables capture parameter co-constraints, specifying the set of units of measurement, body sites, and enumerated values that may be associated with a given parameter, thus enabling even more rigorous validation of exchanged medical device semantic content.

Each of these profiles is defined in full detail in the IHE PCD Technical Framework.

Profile and white paper development is also active in the following areas:

- **[DPI] Device Point-of-care Integration** brings focus on device connectivity around a patient-centric point-of-care, including "first link" interfaces between devices or a device manager / supervisor system. This activity includes initial development of a white paper, followed by a number of proposed profiles such as: discovery and association, data reporting, symmetric (bi-directional) communication, and external control.
- **[MEM] Medical Equipment Management** investigates the question of how health I.T. might support the activities of clinical engineering / biomedical engineering staff, improving quality and workflow efficiency. Key topics include unique device identification, real-time location tracking, hardware/software configuration and patch management, battery management, and more.
- **[PCIM] Point-of-care Identity Management** is an investigation of the workflows and technical means for associating the right device data with a particular patient, which is a critical patient safety requirement.
- **[WCM] Waveform Communication Management** will extend the [DEC] profile to provide a method for passing near real-time waveform data using HL7 v2 observation messages. For example, passing wave snippets as evidentiary data in an alarm message communicated using [ACM] transactions.