

Testimony by

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Before the Health Information Technology Policy Committee Hearing Regarding the ONC HIT Certification Program

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Panel 4: Private Sector Representatives

HIT Policy Committee Members,

I offer the comments that follow in my role as secretary of the board of Integrating the Healthcare Enterprise (IHE) USA. On behalf of IHE USA I want to thank the committee for the opportunity to comment.

IHE began in 1997 as an initiative, sponsored by the Radiological Society of North America (RSNA) and the Healthcare Information Management and Systems Society (HIMSS), to bring together healthcare professionals and industry to improve the interoperability of health IT systems. IHE now has numerous sponsoring organizations internationally and oversees committees in 11 clinical and operational domains, 24 national committees and over 650 member organizations. IHE promotes the use of standards like HL7, W3C, Oasis, DICOM, LOINC and SNOMED to address specific clinical needs by developing implementation guides called IHE profiles. IHE USA was established as a non-profit organization in 2010 with the mission of promoting adoption of IHE profiles and ensuring the usefulness of IHE in the context of the US health system.

IHE USA conducts a testing process for Health IT developers to help them implement IHE profiles. The testing process culminates in annual events called Connectathons and in vendor self-attestation of the conformance of their products with IHE profiles. The same process is also conducted annually by IHE Europe, IHE Japan and IHE Korea. In the last two years, IHE has begun to expand its testing services to include a product certification program.

Here are some of the elements that distinguish the IHE certification program:

- The IHE certification program grows out of an established peer-to-peer interoperability testing process with more than 15 years of experience and hundreds of vendor systems tested.

- IHE profiles and the IHE testing process focus on interoperability and information exchange. They avoid prescribing detailed functional requirements or evaluating usability, which are considered questions best left to market preference.
- To support its testing process, IHE has developed a testing platform and an extensive suite of testing tools in collaboration with an international team of developers, including the interoperability testing laboratory at the National Institute for Standards and Technology (NIST), other research organizations and commercial developers.
- The IHE Profiles on which testing is based go through a development cycle that includes a period of public comment. Based on feedback from testing a profile may be extensively revised. Only after a profile has been successfully tested at multiple events is it published in final text form. Often profiles go through multiple testing and revision cycles.
 - This annual, cyclical process allows for innovation, refinement of specifications based on real feedback and smooth adoption.
 - The profiles included in IHE certification testing have been selected based on the maturity of the specifications and tooling, as well as national program priorities, industry demand and clinical significance.
- In establishing a certification program, we are partnering with an accredited testing laboratory, ICSA Labs. We have conducted an initial pilot program and are working to establish a clear definition, business plan and administrative structure for a continuing program.
 - We have worked with ICSA and consulted with a number of experts on conformance assessment and attestation to develop a certification framework based on industry standard approaches including ISO/IEC Guide 65 and ISO 17025.
 - Through this process, we have evaluated carefully the increased testing and administrative requirements for certification, including product surveillance, a new area for IHE and its testing participants.
- The IHE certification program will be implemented as a coordinated set of regional programs administered by IHE USA, IHE Europe, and potentially other national IHE organizations.
- The IHE profiles on which these programs are based are international in scope and common across all the programs, and IHE is developing a schema to ensure uniformity and reciprocity in these programs.
- The IHE certification program is being implemented incrementally with the intent to grow over time based on demand and strategic priorities.
- The IHE certification program is designed to be complementary with certification programs of ONC in USA and similar national programs in other countries.
 - Patient Care Device testing is an area where IHE has focused initial certification efforts, and an example of how IHE is able to provide detailed testing that falls outside the current focus of ONC certification.
 - IHE has developed detailed specifications in other areas including public health data registries and diagnostic systems in radiology, laboratory, cardiology, pathology, eye care and others that we are likely to add to our certification program over time.

- IHE is working to coordinate its roadmap and timelines for profile development and testing with ONC priorities. Current examples of this effort include work to incorporate support of the Structured Data Capture initiative in IHE profiles and revision of the IHE Healthcare Provider Directory (HPD) profile to accommodate the federated model promoted by the S&I Framework.
- The IHE certification program is voluntary and based on vendor demand. Vendors can choose which certification offerings apply to them based on their market participation .

The experience we have gained through this process leads IHE to recommendations similar to many provided by other commenters today. We believe that to achieve the greatest success the ONC program should:

- Ensure that test methods are developed with sufficient time and resources to provide quality, stability and detailed coverage.
- Focus on baseline functional requirements and especially on testing standards-based interoperability. Leave room for innovation above the bar.
- Leverage complementary voluntary testing programs by organizations like IHE for their ability to extend testing to emerging capabilities and specialty areas of healthcare.
- Continue to work with established standards bodies (including IHE, HL7, DICOM and others) to develop and disseminate the standards that provide the foundation for certification criteria.

Again, IHE is very grateful to the committee for this opportunity to comment.

Sincerely,

/s/

Christopher Carr

Secretary, IHE USA Board