Statement of EHR Association
HIT Standards Panel - Clinical Operations Workgroup
Medical Device Hearing – Device Accuracy and Integrity
Washington, DC
March 28, 2011

Good afternoon, I'm Charles Parisot, the Interoperability and Standards Working Group Chair of the Electronic Health Record (EHR) Association. I work for GE Healthcare, but will not be representing viewpoints specific to GE, but rather viewpoints from the EHR vendor community.

The EHR Association is a strong supporter of the HITECH Act and the work of the HIT Standards Committee.

I'm especially pleased to be testifying with such distinguished colleagues in this Interoperability and Data Integration Panel.

EHR vendors' experience with healthcare devices and device interoperability has evolved significantly over the past few years. It has grown from a limited number of projects in a few large hospitals to an increased demand and users' expectations, now covering a broader spectrum of inpatient facilities and even ambulatory practices.

Interoperability should be about bringing medical device data into the EHR, not to connect medical devices into EHRs.

The industry has been attempting to standardize the connection of medical devices for over 20 years, with little success. The breakthrough came a few years back, from the Integrating the Healthcare Enterprise (IHE) Patient Care Devices domain. The IHE, with its simple and pragmatic approach to interoperability, realized that there was generally some sort of "intermediary node" between the medical device and the EHR system. Standardizing the device to the intermediary interface was difficult and complex work, and touched on a sensitive area relative to patient safety. In contrast, standardizing the interface between the intermediary node and the EHR system was easier and of much higher value.

This insight generates two key points that we will further develop in this testimony:

- ⇨ Interoperability standards from the intermediary node to the EHR system are rapidly becoming more mature.
- ⇨ The interoperability standards that are most relevant and important to the meaningful use of EHR technology are those related to bringing medical device data from any intermediary node into the EHR, not those to connect medical devices to intermediary nodes.

The convergence of interoperability implementation specifications and standards for clinical devices and home devices has been a major breakthrough.

Medical devices used for personal health and wellness and those used for clinical care support significantly different settings and regulatory environments. The associated quality processes also differ across these different settings. In 2008, it became clear that there were critical commonalities between the interoperability associated with device data flows for personal use and those for clinical use. This finding was especially true between the intermediary node (a cell phone, set-top box, or the clinical gateway, nursing station) and the EHR or health information management system.

This interface, called the WAN Interface by the Continua Health Alliance, or the Device Enterprise Communication (DEC) Profile by IHE, has been the focus of much collaboration between IHE and Continua, and is now completely specified. Both rely on a subset of the HL7 V2.6 standard that was profiled carefully by the IHE PCD-01 transaction and the IHE Rosetta Terminology Mapping. These implementation specifications are consistent and now formally approved by both organizations. Of importance is that in these implementation specifications, there is sufficient metadata to track explicitly the data origin (patient-collected data vs. provider-collected data) and device identification.

In conclusion, this convergence of interoperability is likely to remove one of the primary barriers to standards-based interfacing of medical device data into EHRs, and will bring benefits for both device data coming from the home and clinical device data coming from within the care provider organizations. Boosting the adoption of standards and profiles (PCD-01 and RTM) should be an achievable goal given their breadth of applicability, with the support of over 300 different clinical and home devices.

A recommendation for inclusion of Interoperability data (health data from devices) standards.

We see a consensus now established on the applicable standards to bring device data into EHRs:

- ⇨ HLV2.6 as profiled by the IHE PCD-01 implementation specification
- ⇨ IEEE terminology and UCUM, profiled in a device-specific way by the Rosetta Terminology Mapping implementation specification

We believe that these standards provide a solid foundation to proceed for meaningful use-related standards and certification criteria. The critical issue is what is appropriate for Stage 2 of meaningful use given the regulatory timing issues that the EHR Association and others have identified, and that were discussed by the HIT Policy Committee Meaningful Use Workgroup on March 22. The testing tools are now mature and we believe that, as demonstrated at the January 2011 IHE Connectathon, sufficient stability has been achieved to proceed, with several vendors on both sides of the interface expressing commitment to deliver products with compliant interfaces in the coming year or so.

However, we would not recommend engaging with the full breadth of these standards and implementation specifications (over 300 home and clinical devices are supported in RTM). We propose the following approach:

1. The HIT Policy Committee should identify a few device-related patient safety and/or quality issues to be measured or reported for in meaningful use for Stage 3.
2. The HIT Policy Committee should identify a small list (3 to 5) of corresponding medical devices in order to provide focus to the providers and vendors.
3. The HIT Standards Committee should identify HL7V2.6 plus implementation specifications (IHE PCD-01 and the corresponding RTM entries - containment/terminology/units subsets) as the applicable standards. If device data transits from the home over the Internet, use the IHE-ATNA specification (TLS-based), which is also specified by Continua.
4. Announce these plans with sufficient lead time to allow (1) device and intermediaries manufacturers, and (2) EHR vendors and providers to accelerate their alignment and deployment on the above standards and implementation specifications.
5. Announce this direction in the proposed and final rules for Stage 2, but for applicability for Stage 3.

We look forward to working cooperatively with HHS and the Policy and Standards Committees in support of recommendations around the introduction of interoperability for medical device data into EHR systems.

Thank you very much.