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**Written Testimony of**
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**Before the**
**Clinical Operations Workgroup of the**
**Health IT Standards Committee**

**Medical Device Hearing**
**Barriers and Enablers for Medical Device Interoperability**

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On behalf of Philips Healthcare, a Division of Philips Electronics North America Corporation, we would like to thank the Clinical Operations Workgroup of the Health Information Technology Standards Committee for the opportunity to participate on the Interoperability and Data Integration panel and provide testimony for the Medical Device hearing.

Philips Healthcare operates four main business groups: Patient Care and Clinical Informatics, Imaging Systems, Home Healthcare Solutions, and Customer Services. Philips product lines include technologies in clinical decision support solutions, radiology and cardiology imaging and information management systems, patient monitoring systems, special care unit and departmental information systems, remote monitoring (home telehealth), medication dispensing, sleep therapy, general X-ray, ultrasound, magnetic resonance imaging, computed tomography, nuclear medicine including positron emission tomography, personal emergency response systems, anesthesia and ventilation systems, and cardiac resuscitation products.

Philips is one of the world's largest manufacturers of critical care systems, medical monitoring, diagnostic, and therapeutic products. EMRs and EHRs need to interface with virtually all of our health care devices. We have vast experience in such integration, and together with our customers have a critical interest in reducing the difficulty and cost of establishing these interfaces.

Further, we believe it is critically important for this committee to move as swiftly as possible to define medical device standards for interoperability so that standards and certification criteria can be developed to support the certification of medical devices for current and future stages of meaningful use under the HITECH Act. We come to the table ready to provide expertise to help identify and define the standards for interoperability that are required for certification and inclusion of medical devices in meaningful use.

Philips Healthcare is dedicated to providing solutions designed around the needs of our customers and patients. We believe we can make a difference by removing boundaries in healthcare with our innovative and affordable technology solutions throughout the entire care cycle.

## All Panels – General Questions

1. **What is your experience with health care devices and device interoperability? Have you experienced specific problems where standards might contribute to solutions?**

**Our Experience**

- Philips Healthcare has been developing solutions for integrating healthcare device data with clinical information systems for over 20 years. These solutions allow 3rd party devices to integrate with both our patient monitoring solutions, and our own and 3rd party clinical information systems.

- Philips has also been a leader in developing and promoting open interface standards for medical device interoperability. We were an originating promoter of the Continua Health Alliance. We volunteer, contribute to, and lead numerous workgroups and standards development organizations such as Integrating the Healthcare Enterprise (IHE), IEEE, and Digital Information and Communications in Medicine (DICOM). Additionally we can leverage Philips expertise in developing, testing, and certifying standard-based interoperability in consumer electronics and communications.

**The Problems**

- The interoperability challenge: A lack of common nomenclature results in expensive mapping between device interface specifications and the EHR. It is not just the syntactical integration enabled by standards (IEEE 110073, HL7, Web Services), but also semantic integration that interoperability guidelines enable. Notably the IHE Patient Care Device (PCD) domain and Continua Health Alliance consortia are making significant strides in this area, and Philips has been an active contributor to these organizations and their interoperability objective.

- Without standards, integration tends to be deployed as a one-off solution, frequently resulting in project delays, unanticipated cost, and possible quality problems.

- An additional problem is the non-uniform legal treatment of interface standards. Some companies have declared their interface specifications to be proprietary, adding another level of complexity to establishing interfaces between products made by competing companies.

  For example, Philips appeared before the European Commission to secure the right to interface our products with EHRs and therapy devices of one of our competitors. If the Committee were to recommend or mandate interfaces that are non-proprietary, it would reduce the cost and complexity of establishing interfaces.

**2. Are there areas where standards are more mature or less mature?**

- True interoperability requires that systems not only integrate at a network connectivity layer but also exchange messages that contain content that can be understood by the receiving system. Many standards are mature at both the network connectivity layer (e.g., TCP/IP) and at the message syntactic layer (e.g., HL7). Additionally many standards exist that allow for message content to be understood (e.g., SNOMED). Systems need to use multiple standards to achieve interoperability goals and increase adoption rates.

- Document exchange-based standards are also fairly mature, but the standardization of the content is highly dependent on use case (e.g., image-based exchange).

- Organizations such as IHE and Continua have been leading efforts to increase adoption of these standards by bringing together providers and venders to create solution profiles to that address common healthcare interoperability challenges. Many of these profiles are becoming quite mature (e.g., communicating device data to the EMR/EHR) as evidenced by the number of vendors supporting the capability at IHE Connectathons. Unfortunately, implementation of these profiles lags in industry.

- Standards in the out of hospital (e.g., emergency medical services) environment are nascent and will become increasingly important as a more holistic view of the patient episode is used for measuring and improving quality and efficiency of care.

3. **What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?**

   - Semantic interoperability, in addition to syntactical standards, is needed to ensure that information exchanged between systems can be understood as part of clinical decision support capabilities. Collaborative work across the various standards bodies (e.g., IHE and Continua) should be encouraged, so that implementation by the provider is ultimately based on agreed upon interoperability profiles.

   - RFPs and regulatory norms should focus on interoperability (by mandating the use of applicable interoperability guidelines), and not just on standardization.

4. **What do you see as key barriers to effective use of health care devices to advance health and wellness?**

   - Information should not just be sent *to* the EHR, but also be made available *from* the EHR. Many clinical problems can be best addressed in clinical devices but need supporting information from the EHR. For example, advanced alarm features for patient monitors could be developed if the monitor were to receive information on a patient's current diagnosis and administered medications from the EHR or EMR. Other examples can be found in chronic care where post-discharge risk monitoring and long-term compliance management would benefit from information previously collected during hospital and other clinical episodes, which information is currently 'locked' in the various EHRs.

5. **If you could wave a magic wand to effect one change to enable more effective and widespread use of health care devices, what would that be?**

   - Philips vision is that devices will be ubiquitous – available wherever needed – and data communications will be seamless and based on standards. These standards should interoperate across the entire continuum of care.

   - To realize this vision, incentives and reimbursement need to match and support the adoption and implementation of standards across all care settings -- from home, to doctors' office, to emergency medical services (EMS), to and through the hospital, and back to the home.

   - Further, financial barriers must be removed. For example, legislating reimbursement of home telehealth care models would encourage large scale roll-out of telehealth solutions. There is evidence from numerous

small-scale pilots that suggests telehealth is technically and clinically effective and efficient.

## Interoperability/Data Integration Panel

**8. What data about devices is needed in EHRs?**

- The following items are relevant to many use cases:
  - Device settings
  - Relevant physiological data samples with time stamps, which could be simple numerical measures (e.g., vital signs) or graphical representations that reflect both value and time (e.g., waveforms, maps and trends)
  - The data about devices that is necessary for full discoverability of the data source should include device ID, model, and unique device identification number
  - Alarms and alerts and the clinical acknowledgement of same

- Data needed in EHRs is highly dependent on the intended use of the data within EHRs (e.g., data that is used for documentation and retrospective reporting needs to be highly accurate and representative of key events of the patient stay).

- It is also important to consider good system design and separation of concerns to ensure integration requirements do not become overly complex. Many monitoring and therapy use cases require very reliable, low-latency communication links and time synchronization between data sources.

- It is more important to consider the specific use case that needs to be addressed rather than simply storing all of the data that is collected from a patient during a stay.

**9. Questions related to Meaningful Use**

**a. How would device data in EHRs affect Stage 1 measures?**

- Automated device data collection can improve efficiency and accuracy of some meaningful use measures.

- Vital sign data and collection is a critical component of the patient's medical record.

- Device data can support quality measure reporting too; specifically, blood pressure measurement to support quality measures around

hypertension and stroke, and documentation and reporting of cardiac rhythm in support of quality measures covering anticoagulation for A-fib/flutter. Device data can either affirm or rule out certain quality measure compliance initiatives such as ventilator-associated pneumonia bundles. Given the potential patient safety issues presented by manual collection and entry of vital signs data into the EHR, we believe that automatic integration of such device data will be critical to improved outcomes and quality patient care.

**b. What device-related patient safety and/or quality issues should be measured or reported?**

- Clinical response to, and acknowledgement of, alarms and results will be useful elements of future quality measures. As such, these events should be recorded and made available for inclusion in systems responsible for aggregating and reporting patient quality and safety measures.

- Records of alarm settings, records of device malfunction, and service and repair history may also be useful measures to report.

**10. What is the impact of the recent FDA MDDS rule on device integration with EHRs?**

- We believe that the transition of the health record from paper to electronic form presents unique opportunities for improvement in care as well as some potential areas of risk that need to be fully considered in any rule. Automating the incorporation of device data into the EMR is not equivalent to automatically printing the data in a paper record. In the example of a system that automates the recording of device data for the paper record, the paper record was the end product of the interaction.

  The data contained within the paper record could not be used for secondary purposes as it can be in today's EHR environment. The potential secondary uses of regulated device-sourced EHR data include alerting applications, trending and display applications, and clinical decision support applications. Systems that use this data for such life-critical purposes as order communication, alerting, and CDS should be designed with as much control of quality and safety as the source devices that generate the original data.

  Incorporating this information into the EMR to help in the care of patients is a key element in creating patient care benefits from the

automation of the health care record. However, systems that make secondary use of this data (beyond merely displaying the values) need to be as reliable and predictable as the regulated devices from which the data is taken. Taking data from the regulated patient care devices and using it for similar purposes as the source device (display, trending, alerting, and clinical decision support) implies to the public that a comparable level of oversight and assurance of safety was incorporated into development and testing of the receiving system.

Therefore, we agree with the approach taken by the FDA in the MDDS rule and support the FDA's efforts to ensure the safety of the public by closely monitoring this important part of the Healthcare IT environment.

**11. How should integration of home and remote monitoring with EHRs be addressed?**

- The integration should be a service-to-EHR integration, not a direct device-to-EHR integration, because of the remote setting.

- We recommend interoperable (IHE, Continua), standards-based (HL7, IEEE 11073, etc.) integration profiles should be considered and used instead of vendor-to-vendor 1:1 ad-hoc solutions, e.g.,
    - HL7 v2.6-based profiles for device communication, as profiled by both IHE and Continua
    - HL7 CDA r2 PHMR for personal health monitoring reports exchange

- Today's integrations are primarily with individual EHRs at the various clinical sites that use home/remote monitoring. That model should be extendible to integrated care organizations and national health networks. For example, in the UK, the National Health Service program, Connecting for Health (NHS CfH), has started telehealth integration profiles for their national health infrastructure.

**12. How should integration of regulated clinical devices with EHRs be addressed?**

- Automated incorporation of regulated device-sourced patient information into health information technology (HIT) systems is an essential element of a comprehensive health record. And, the new MDDS rule is a good first step. We believe that systems that aggregate and report regulated device-sourced patient information should be subject to similar quality and safety standards as the source devices.

- It is important to ensure integration is done along regulated boundaries that are not ambiguous to the clinical user. For example, if alarm reporting is integrated into the EHR, the user should clearly know whether this is primary or secondary alarming or simply documentation. If waveforms are displayed within the EHR, the user should know the latency and time synchronization associated with their display relative to other parameters.

- Regulated devices are designed to ensure patient-safe medical procedures, and integration needs to have the same safeguards applied. IEC 80001 is a good model that could potentially be used and or extended to apply to EHR integration.

**13. Please consider comments on identification of devices related to use of EHRs.**

**a. In supply chain management and other management processes**

- Unique device identification in supply and quality management is clearly a priority and should be continued.

**b. In safety processes including identification of recalled implanted devices**

- It should be possible to uniquely identify medical devices that are currently associated with a patient's care (e.g., implantable devices). It should also be possible for a patient to get these device identifiers through their electronic health record. Other devices that were only transiently involved with the patient's care during a hospital stay are less likely to be relevant to any future patient event. It will be important to measure the additional complexity of tracking these devices in the EHR versus the additional benefit provided to the patient and healthcare system.

**Conclusion**

Incorporation of regulated device-sourced patient information into health information technology (HIT) systems is an essential element of a comprehensive electronic health record. Philips has been a leader in developing and promoting open interface standards for medical device interoperability. We look forward to working with the Clinical Operations Workgroup as it continues to develop these important recommendations to the HIT Standards Committee and the National Coordinator.